Open-Label, Multi-Center, Randomized Study of Anti-CCR4 Monoclonal Antibody KW-0761 (mogamulizumab) Versus Vorinostat in Subjects with Previously Treated Cutaneous T-Cell Lymphoma

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Statistical Analysis Plan Signature Page

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Summary of Revisions

- Updated Sections 3 to 5 to reflect changes made in protocol amendments 5, 6, and 7.
- Updated Section 6.11.1.1 to clarify that for the primary efficacy variable progression-free survival (PFS), documented progression include disease progression in any compartment based on Investigator's assessment per CTCL response criteria or documented disease progression reported during the follow-up period. The date of progression will be the earliest date at which documented disease progression can be declared.
- Updated Section 5 to show the global composite response score definitions. Clarified the overall response rate is based on the global composite response score.
- Changes were made to Section 6.11.1.2.1 to clarify that confirmation of complete response and partial response is required for the overall response rate. In addition to the confirmed overall response rate, the confirmed and unconfirmed overall response rates will be summarized. Added summaries efficacy summaries by disease type.
- Added clarifications in Section 6.11.1.2.2 on the scheduled time points for QoL evaluation. Added additional time points to summary table.
- Updated Sections 6.11.1, 6.11.1.4, and 6.11.2.5 to include time to treatment failure as an exploratory efficacy variable.
- Updated Section 6.11.1.4 to omit statement that each subject would be followed in the study for a minimum of two years to generate information on overall survival.
- Updated Section 6.11.2.2 to add a sensitivity analysis for the primary efficacy variable PFS by including clinical progression from PFS events.
- Updated Section 6.11.2.4 to clarify that duration of response and time to response are summarized only for subjects with confirmed complete response or partial response. Added concordance analysis between the investigators assessment and the independent review of best overall responses.
- Updated Section 6.11.2.5 to include additional exploratory analysis for PFS between subjects with any exposure to KW-0761 versus subjects with vorinostat only.
- Updated Sections 6.11.2.6, 6.11.2.7, and 6.15 to remove CCR4 related analysis and to indicate that a separate analysis plan will be prepared to detail the CCR4 analysis.
- Updated Section 6.12.1 to include summary of exposure-adjusted incidence rate and exposure-adjusted event rate for special adverse events.
- Changes were made to Section 6.14 to revise immunogenicity analysis.
- Revised to reflect the current plan for presenting PK data. Descriptive statistics will be presented for the PK data.
- Revised summary of ECOG performance status from worst score during randomized treatment to mean and mean change from baseline summaries every 8 weeks.
- Added testing for quality of life assessment beyond the 6-month assessment period.
- Added exploratory analyses of Overall Survival adjusting for crossover.
- Updated company name.
- Incorporate other minor clarifications and typographical corrections.

Table of Contents

List of Abbreviations

Abbreviations

aCRF	Annotated case report form
AE	Adverse Event
ANC	Absolute neutrophil count
ANCOVA	Analysis of Covariance
ATC	Anatomical Therapeutic Chemical
CCR4	CC chemokine receptor 4, chemokine (C-C motif) receptor 4
BMI	Body mass index
BSA	Body surface area
CMH	Cochran-Mantel-Haenszel
CR	Complete response
CRF	Case Report Form
CS	Clinically significant
CSR	Clinical Study Report
CT	Computerized Tomography
CTCL	cutaneous T-cell lymphoma
CTIVRS	ClinTrak Interactive Voice/Web Response System
DOR	Duration of response
DSMB	Data Safety Monitoring Board
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EORTC	European Organization for Research and Treatment of Cancer
EQ-5D-3L	European quality of life 5 dimensions 3 levels
EWB	Emotional well-being
FACT-G	Functional Assessment of Cancer Therapy-General
FWB	Functional well-being
ICH	International Conference on Harmonisation
IHC	Immunohistochemistry
IPCW	Inverse probability of censoring weighting
IR	Independent Reviewer
ISCL	International Society of Cutaneous Lymphomas
ITT	Intent-to-Treat
iv	Intravenous
KKD	Kyowa Kirin Pharmaceutical Development, Inc.
LOCF	Last observation carried forward
LS	Least squares
MedDRA	Medical Dictionary for Regulatory Activities
MF	Mycosis fungoides
mg	Milligram
msec	Milliseconds
mSWAT	modified Severity Weighted Assessment Tool
NCI-CTCAE	National Cancer Institute- Common Terminology Criteria for Adverse Events
NCS	Not clinically significant

Abbreviations

ORR	Overall response rate
OS	Overall survival
PD	Progressive disease
PFS	Progression-free survival
PK	Pharmacokinetics
PR	Partial response
PS	Performance status
PT	Preferred Term
PWB	Physical well-being
QoL	Quality of life
QTcB	QTc Bazett correction
QTcF	QTc Fridericia correction
RPSFT	Rank-reserving structure failure time
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SAS®	Statistical Analysis Software
SD	Standard Deviation or stable disease
SOC	System Organ Class
SS	Sézary Syndrome
SWB	Social/family well-being
SWAT	Severity Weighted Assessment Tool
TBSA	Total body surface area
TEAE	Treatment-Emergent Adverse Event
TLFs	Tables, data listings, figures
TTF	Time to treatment failure
TTR	Time to response
US	United States
USCLC	United States Cutaneous Lymphoma Consortium
VAS	Visual analog scale
WBC	White blood cell count
WHO	World Health Organization

1 INTRODUCTION

This Statistical Analysis Plan (SAP) has been developed after review of Kyowa Kirin Pharmaceutical Development, Inc. (KKD) Protocol 0761-010 (original version dated 19 June 2012, Amendment No. 1 dated 09 July, 2012, Amendment No. 2 dated 19 February, 2013, Amendment No. 3 dated 03 April, 2013), Amendment No. 4 (dated 14 November, 2013), Amendment No. 5 (dated 05 March, 2014), Amendment No. 6 (dated 04 March, 2015), Amendment No. 7 (dated 09 March, 2016), the corresponding annotated case report form (aCRF), and the raw Statistical Analysis Software (SAS®) data schemas. This SAP describes the analysis sets and specific details for the statistical methods to be used for the analysis and reporting of all efficacy, safety, biomarker, and immunogenicity data collected during the conduct of Protocol 0761-010. This SAP supersedes the statistical considerations identified in Protocol 0761-010 and where considerations are substantially different, they will be identified as such in this document. This SAP has been developed and finalized prior to database lock of the clinical database for Protocol 0761-010. If additional analyses are required to supplement the planned analyses described in this SAP, they may be performed and will be identified in the Clinical Study Report (CSR).

This SAP is being written with consideration of the recommendations outlined in the International Conference on Harmonisation (ICH) E9 Guideline entitled "Guidance for Industry: Statistical Principles for Clinical Trials"[1] and the most recent ICH E3 Guideline entitled, "Guidance for Industry: Structure and Content of Clinical Study Reports".[2]

2 OBJECTIVES

2.1 Primary Objective

The primary objective of this study will be:

- To compare the progression free survival (PFS) of KW-0761 versus vorinostat for subjects with relapsed or refractory cutaneous T-Cell Lymphoma (CTCL).

2.2 Secondary Objectives

The secondary objectives will be:

- To compare the overall response rate of KW-0761 versus vorinostat in subjects with relapsed or refractory CTCL;
- To evaluate and compare improvements in Quality of Life (QoL) measurements Skindex-29, Functional Assessment of Cancer Therapy-General (FACT-G) and European

Quality of Life 5 dimensions 3 levels (EQ-5D-3L) for subjects receiving KW-0761 versus vorinostat;

- To evaluate and compare improvements in the Pruritus Evaluation (Likert scale & Itchy QoL) for subjects receiving KW-0761 versus vorinostat;
- To estimate the duration of response (DOR) for both the KW-0761 and vorinostat arms for those subjects with relapsed or refractory CTCL responding to treatment;
- To determine if subjects who relapse on vorinostat can achieve response upon cross over to treatment with KW-0761;
- To further assess the safety of KW-0761;
- To describe the immunogenicity of KW-0761.

2.3 Exploratory Objectives

The exploratory objectives will be:

- To compare the overall survival of KW-0761 versus vorinostat for subjects with relapsed or refractory CTCL;
- To conduct exploratory evaluation of KW-0761exposure-response relationships.

3 STUDY DESIGN

3.1 Overview of Study Design

This open-label, multi-center, randomized, Phase 3 study will enroll subjects with previously treated CTCL including mycosis fungoides (MF) and Sézary Syndrome (SS). Approximately 317 subjects may enroll in this study over a period of 24 months. The primary analysis will be conducted when 255 total progression-free survival events have been observed or 24 months after the last randomized subject's first dose, whichever comes first. It is anticipated that approximately 75 investigational centers in the US, Europe, Japan and Australia will participate in this study.

3.2 Treatment Plan

3.2.1 Assignment to Study

After a subject signs consent, screening numbers should be assigned by the Investigator (or designee) using ClinTrak Interactive Voice/Web Response System (CTIVRS). Once assigned, numbers for any screen failures or non-treated, non-evaluable, or discontinued subjects will not be re-used.

A subject who meets all entry criteria will be randomized in a 1:1 ratio to receive KW-0761 or vorinostat. The randomization to treatment groups will be stratified by disease type (MF or SS) and disease stage (IB/II or III/IV). When a subject is determined to be eligible for randomization the Investigator (or designee) will contact CTIVRS to obtain the randomization assignment for the subject.

3.2.2 Study Treatments

In this protocol, study treatments are KW-0761 and vorinostat. Subjects will be randomized to the study drug, KW-0761 or comparator, vorinostat, in a 1:1 ratio.

3.2.2.1 Study Drug: KW-0761 (mogamulizumab)

Treatment can be administered on an outpatient basis. Subjects will receive 1.0 mg/kg of KW-0761 as an intravenous (iv) infusion over at least 1 hour on Days 1, 8, 15 and 22 of the first cycle and on Days 1 and 15 of subsequent cycles. Each treatment cycle is 28 days.

No dose modifications of the KW-0761 will be permitted in this study. Subjects will not be replaced.

3.2.2.2 Study Drug: Vorinostat (ZOLINZA®)

Treatment can be administered on an outpatient basis. Subjects will take 400 mg orally once daily with food. Each treatment cycle is 28 days.

Management of severe or intolerable adverse reactions may require dose omission, reduction or interruption of vorinostat therapy. Subjects will not be replaced.

3.2.2.3 Duration of Treatment

Subjects may remain in the treatment phase up until progressive disease (PD), drug intolerance or unacceptable toxicity, or until any of the other criteria for study removal are met. Except in cases of unacceptable toxicity or drug intolerance, every effort should be made to ensure the subject remains in the study until disease progression.

In cases where the definition of PD or relapse is met but the clinical impression is questionable, subjects may remain on study until the next evaluation (4 weeks later if questionable finding in skin or blood; 8 weeks later in first year and 16 weeks later after Year 1 if questionable finding in lymph nodes or viscera, with at least stable disease in other compartments) to avoid a subject being removed prematurely from the study. If PD is confirmed at this subsequent evaluation, subject should be discontinued from treatment. If

PD is not confirmed at this subsequent evaluation, the subject may remain on study.

This course of action only applies to cases where the clinical impression is questionable; subjects in frank or obvious PD in any compartment should be discontinued from protocol therapy.

If clinical progression is noted at any time prior to the scheduled assessments for efficacy, the assessments (CT, mSWAT, skin photographs and flow cytometry) should be done at that time to fully document disease progression. CT must be performed even if previously negative at baseline.

If the subject experiences an overall complete response (CR), the subject may continue treatment for up to 12 months or until progression, whichever comes first.

3.2.2.4 Cross-over to Study Drug KW-0761

Subjects who have received at least two full treatment cycles and demonstrate progression of disease on treatment with vorinostat at the 8 week (cycle 2, Day 26-28) assessment, or anytime thereafter, may cross over to treatment with KW-0761 after discussion with Medical Monitor or designee and receipt of approval for cross over from KKD. All subjects must undergo the full extent of disease evaluations (including computerized tomography (CT) scanning) to document PD prior to crossover.

For subjects who are unable to tolerate the toxicities associated with vorinostat treatment, dose reduction should be initiated in an attempt to have the subject complete two full cycles of treatment. If the subject is unable to tolerate treatment with vorinostat despite attempts at dose reduction and has not had documented disease progression, the subject may receive KW-0761 after consultation with the Medical Monitor or designee and subsequent approval documentation from the Sponsor.

Drug intolerance is defined as:

- A serious adverse event (SAE) attributed to the drug;
- $\geq$ Grade 3 adverse events (AEs) excluding inadequately treated nausea, vomiting and diarrhea and alopecia.

4 SUBJECT SELECTION

This study will enroll subjects with CTCL who have failed at least one prior course of systemic therapy.

The detailed inclusion and exclusion criteria are defined in Section 3 of the protocol.

5 STUDY ASSESSMENTS

5.1 Efficacy Evaluations

Response in skin and blood will be evaluated every 4 weeks during treatment. In the first year of treatment, response in lymph nodes and viscera and the overall global composite response (including skin, blood, lymph nodes, and viscera) will be documented at 4 weeks after the start of study treatment (end of Cycle 1) and every 8 weeks thereafter (Cycle 3, 5, etc.). After the first year, response in the lymph nodes and viscera and the overall global composite response will be documented every 16 weeks (Cycle 17, 21, etc.).

For those subjects who cross over from the vorinostat arm to KW-0761 treatment, response within the second arm of the study will be measured from the first day of dosing with KW-0761. Baseline measurements for this arm are considered to be those taken at the last assessment which documented progression on vorinostat or if repeated, assessment completed closest to and before the first KW-0761 infusion (i.e., mSWAT done on Cycle 1, Day 1 is the new baseline).

Prior to starting study treatment, visual inspection of the skin with photographs and measurements Severity Weighted Assessment Tool (SWAT), assessment of CT images and hematological examinations will be done to document extent of disease. Skin disease will be evaluated using a modification of the SWAT. Response for skin will be based on modified SWAT (mSWAT) scores. In addition, pruritus will be evaluated using a Likert scale and Itchy QoL. Lymph nodes and visceral disease will be evaluated by CT. The response in blood will be assessed by flow cytometry.

The response in all compartments (skin, blood, lymph nodes and viscera, as applicable) and overall response will be assessed, except as otherwise noted, in accordance with the response criteria determined by consensus of the International Society of Cutaneous Lymphomas (ISCL), the United States Cutaneous Lymphoma Consortium (USCLC) and the Cutaneous Lymphoma Task Force of the European Organization for Research and Treatment of Cancer (EORTC) as noted in Table 5.1-1 below.[3]

Table 5.1-1 Global Composite Scoring System

Global Score	Definition	Skin	Nodes	Viscera	Blood
CR	Complete disappearance of all clinical evidence of disease	CR	All categories have CR/NI		
PR	Regression of measurable disease	CR	All categories do not have a CR/NI and no category has a PD		
		PR	No category has a PD and if any other category involved at baseline, at least one has a CR or PR		
SD	Failure to attain CR, PR or PD	PR	No category has a PD and if any other category involved at baseline, no CR or PR in any		
		SD	CR/NI,PR,SD in any category and no category has a PD		
PD	Progressive disease	PD in any category			
Relapse	Recurrence of disease in prior CR	Relapse in any category			

NI=non-involved

If clinical progression is noted at any time prior to the scheduled assessments for efficacy, the assessments (CT, mSWAT, skin photographs and flow cytometry) should be done at that time to fully document disease progression. CT must be performed even if previously negative at baseline.

5.1.1 Evaluation of Skin Disease

5.1.1.1 Skin Biopsy

5.1.1.1.1 CCR4 Expression

A skin biopsy will be taken at baseline for determination of CCR4 expression by immunohistochemistry (IHC). In the event it is not possible to obtain a skin biopsy, use of an archived sample (taken within 6 months prior to treatment) may be allowed with prior authorization from the Sponsor. To determine if vorinostat alters CCR4 expression, investigators are strongly encouraged to obtain an additional skin biopsy for the determination of CCR4 expression, prior to treatment with KW-0761, in subjects who cross over from treatment with vorinostat.

5.1.1.1.2 Disease Status/Other Biopsy Recommendations

Subjects with clinical features suggestive of large cell transformation must have a biopsy performed within 4 months prior to Cycle 1 Day 1 to rule out transformed disease.

Skin biopsies at the end of the cycle and to confirm a CR are optional and can be performed at the discretion of the investigator. Analysis of these biopsies will be done by the pathologist at the study site.

Additional translational assessments may be performed to further characterize the response in skin on any biopsy samples obtained.

5.1.1.2 Skin Photographs

All involved areas that are representative of the subject's extent of disease, will be selected at baseline and measured and photographed using a digital camera provided by Canfield. In addition, half-body global photos (waist to feet, waist to top of head and sides) will also be obtained.

Skin photographs should be obtained prior to administration of study drug on Day 1 of the first treatment cycle and then as specified in the Study Procedures tables in the protocol.

5.1.1.3 Modified Severity Weighted Assessment Tool (mSWAT)

Skin lesions and erythema will be evaluated using the mSWAT.

The mSWAT is an objective, quantitative, severity-weighted method to assess the extent of skin lesions. An mSWAT score is derived by measuring each lesion as a percentage of total body surface area (%TBSA) and multiplying it by a severity-weighting factor (1=patch, 2=plaque, 4=tumor). All individual numbers are then added to produce a total score.

5.1.1.4 Response Criteria for Skin

Response in skin will be determined by changes in mSWAT score as specified in the protocol. Responses (CR and PR) must be confirmed for a minimum of 4 weeks.

5.1.1.5 Pruritus Evaluation

The extent of pruritus can have a significant impact on the subject's QoL. A Likert scale will be completed by each subject to assess their degree of pruritus at the visits specified in the Study Procedures tables. The Itchy Quality of Life questionnaire will also be completed by the subjects at these visits to further evaluate the impact of pruritus on their QoL.

Medications taken to treat pruritus will be documented.

5.1.2 Evaluation of Blood Disease

5.1.2.1 Flow Cytometric Analysis

A peripheral blood sample will be used to evaluate circulating malignant T-cells and further assess immune cells in the blood. Samples will be sent to a central laboratory designated by the Sponsor.

5.1.2.2 Response Criteria in Blood

In subjects with blood involvement, response in blood will be determined based on criteria as specified in the protocol. All blood responses (CR and PR) must be confirmed for a minimum of 4 weeks.

5.1.3 Evaluation of Disease in Lymph Nodes and Viscera

5.1.3.1 Baseline Tumor Assessments

The baseline tumor burden will be assessed by CT of the neck, chest, abdomen and pelvis within 30 days prior to the first dose of study drug. The Investigator will identify, prospectively, the lesions to be followed to evaluate the subject's response to therapy.

5.1.3.2 Method of Tumor Response Assessment

The same method of assessment and the same technique should be used to characterize each identified and reported lesion at Screening and at reassessment during treatment. Imaging-based evaluation is preferred to evaluation by clinical examination when both methods have been used to assess the anti-tumor effect of a treatment. Lesions evaluated clinically will only be considered measurable when they are superficial (e.g., skin nodules, palpable lymph nodes).

Central review of radiologic images may be performed to confirm the date of disease progression.

5.1.3.3 Determination of Response in Lymph Nodes and Viscera

The Investigator will make a determination of response based on criteria as specified in the protocol. In subjects with lymph node and/or visceral involvement, responses (CR and PR) must be confirmed for a minimum of 4 weeks.

5.1.4 Global Composite Response Score

Overall response will be based on response in each compartment (skin, blood, lymph nodes and viscera) as specified in the protocol. Node, viscera and blood response contributes towards global response only if disease was present at baseline, unless defining global PD which is met by new disease in a previously uninvolved compartment.

Subjects who meet PD criteria in any compartment, or relapse in blood, lymph nodes or viscera, confirmed at two consecutive visits must be discontinued from study treatment due to disease progression/relapse. If subsequent assessment does not confirm PD in any compartment, or relapse in blood, lymph nodes or viscera, subject may continue on treatment. An unconfirmed PD/relapse would not preclude future responses (CR or PR).

If PD is documented in any compartment at any point leading to subject's discontinuation from treatment, the overall global composite score should be completed at that time even if all compartments have not been assessed.

5.1.4.1 Independent Review of Progression

A blinded Independent Review of response data for each subject will be performed to make a determination regarding progression and the date of progression. The nodal and visceral compartments evaluation will be based upon radiologic data. The independent radiology review of radiographic exams will provide an assessment of tumor response and progression for all subjects. A separate radiology charter will detail the roles and responsibilities of the radiology reviewers and how the reads will be performed. An independent reviewer (IR) will assess PFS based on date of progression or death, whichever comes first. For this assessment the independent reviewer will be supplied the results of the independent radiology review, the mSWAT score for each subject, as assessed by the investigator, and the results of central flow cytometry in order to assess blood response, and date of death for subjects who died before progression.

Secondarily, the IR will review the date of any objective responses (CR or PR) for each subject.

The independent review charter identifies the data package that the Independent Reviewer receives to review responses for each subject with baseline and at least on post-baseline measurement in the study.

5.2 Safety Assessments

The safety of KW-0761 and vorinostat will be determined by reported AEs, changes in physical examinations, vital sign measurements, electrocardiograms (ECGs) and laboratory analyses. Safety evaluations will be performed throughout the study. All subjects who received at least one dose, including a partial dose, of study drug will be evaluated for safety.

5.2.1 Adverse Events

All subjects will be assessed regularly for potential occurrence of AEs from the time of signing the informed consent until 90 days after the last dose or initiation of alternative therapy whichever comes first. In all subjects who cross over from vorinostat to KW-0761, the causality of any reported AEs should be assessed for both drugs for 30 days after vorinostat was stopped (or later if the event is considered to be related to vorinostat).

All AEs will be coded by Medical Dictionary for Regulatory Activities (MedDRA, version 15.1). The National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) v4.0 system will be used to grade AEs, both clinical and laboratory.

5.2.2 Clinical Laboratory Evaluations

Clinical laboratory assessments will be performed at the visits specified in the Study Procedures tables of the protocol. A pregnancy test (serum or urine) is to be performed for all women of childbearing potential prior to administration of study medication.

Clinical laboratory assessments are specified in the protocol.

5.2.3 Vital Signs and Body Weight

Vital signs (pulse, respiration rate, temperature, and blood pressure) will be measured, with the subject in the seated position, at the visits specified in the Study Procedures tables of the protocol. Additional vital signs will be obtained if clinically significant signs or symptoms occur.

Weight will be included in vital sign assessments.

5.2.4 Physical Examination

The Investigator will perform a full physical examination at the Pre-treatment (including height at only this visit) and End of Treatment visits and brief physical examinations at other visits specified in the Study Procedures Tables in the protocol.

Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) will be assessed at each exam according to the ECOG PS criteria.[4]

5.2.5 Electrocardiograms

A baseline 12-lead ECG is to be obtained at the Pre-treatment Visit. Follow up ECGs should be performed during the study if clinically indicated and then at the End of Treatment visit.

The Investigator will have the responsibility for evaluating the ECG interpretation in relationship to clinical signs and symptoms and for reaching a medical decision regarding the subject's medical status. If not within normal limits, the ECG findings should be marked "clinically significant" or "not clinically significant" (i.e., "CS" or "NCS") and the ECG should be initialed and dated by the Investigator.

5.2.6 Blood Sample for Determination of Natural Ligands

Blood samples will be drawn to measure the concentration of natural ligands such as CCL17/TARC and CCL22/MDC at the visits specified in the Study Procedures Tables in the protocol. Analysis of samples will be performed by a central laboratory designated by the Sponsor.

5.2.7 Genomic Sampling (For subjects receiving KW-0761 as first assigned therapy only)

A saliva sample will be collected to obtain baseline germline DNA sample to assess Fc-gamma receptor polymorphisms. Exploratory analysis of the effect of this genetic determinant on safety parameters may be performed. Analysis of samples will be performed by a central laboratory designated by the Sponsor.

5.2.8 Immunogenicity (For subjects receiving KW-0761)

Serum samples will be drawn for the determination of anti-KW-0761 antibodies and concentration of KW-0761 at the visits specified in the Study Procedures Tables in the protocol. Analysis of samples will be performed by a central laboratory designated by the Sponsor.

5.3 Pharmacokinetic Assessments

Serum samples will be drawn in subjects who receive KW-0761 (as first assigned therapy or crossover) at the timepoints specified in the Study Procedures Tables in the protocol for

determination of KW-0761 concentration, through Cycle 3 and at the End-of-Treatment Visit. At selected sites, 4 additional samples will be drawn between 6 and 8 hours, and at 24, 48, and 72 - 96 hours after the first infusion on Day 1/Cycle 1 in approximately 10 subjects. All samples will be sent to a central laboratory designated by the Sponsor.

5.4 Quality of Life Assessments

Subjects with CTCL often suffer from the symptoms related to their disease (pain, sleep disturbance, etc.), the social and psychological problems related to sometimes unsightly skin lesions and the burden of living with a chronic disease. In an effort to assess some of these QoL issues, the Skindex-29, FACT-G, and EQ-5D-3L will be administered.

5.5 Follow-Up

- All subjects will be contacted by telephone every 30 days (+/- 7 days) up to 90 days after the last dose of study medication or initiation of alternative therapy, whichever comes first, to confirm any new onset AEs or toxicities. In all subjects who cross over from vorinostat to KW-0761, the causality should be assessed for both drugs for 30 days after vorinostat was stopped (or later if the event is considered to be related to vorinostat).
- After a subject who receives KW-0761 goes off study, if CD4 and CD8 counts are less than 200/mm^3 at the End-of-treatment visit, they will be followed every 3 months (+/- 14 days) until they return to at least 200/mm^3, initiation of alternative therapy, or 1 year, whichever comes first.
- In the absence of disease progression, all subjects or their referring physicians will be contacted every 3 months (+/- 14 days) until documented disease progression or death, or initiation of alternative therapy.
- All subjects or their referring physician will be contacted every 3 months (+/- 14 days) to ascertain survival status.
- All follow up information and attempts to obtain follow up information should be documented in the subject's source record.

5.6 Follow-Up for Subjects Achieving a Complete Response

Those subjects who do not continue treatment after achieving a CR will undergo the following assessments every 8 weeks (+/- 14 days) for the first 6 months (if CR achieved prior to one year on study) and then every 16 weeks (+/- 14 days) thereafter until progression:

- Chemistry/Hematology profile;
- Skin photographs;
- mSWAT;
- Pruritus evaluation;

- Blood sample for flow cytometric analysis;
- CT;
- Overall Disease Response;
- Immunogenicity (for subjects receiving KW-0761).

6 STATISTICAL METHODOLOGY

6.1 General Statistical Consideration

Summary statistics will be presented by treatment arm. For continuous variables, the number of available observations (n), mean, standard deviation (SD), median, minimum, and maximum will be provided. For categorical variables, the frequency and percentage in each category will be displayed. Additionally, the point estimates will be accompanied by the corresponding 2-sided 95% confidence intervals.

For summary statistics, the mean and median will be displayed to one decimal place greater than the original value and the measure of variability (e.g., standard deviation) will be displayed to two decimal places greater than the original value.

Unless otherwise specified, all efficacy and safety analyses will be performed based on the first assigned therapy. For those subjects in the vorinostat arm who cross over into the KW-0761 arm, efficacy and safety data collected during the crossover portion will be presented separately within the KW-0761 crossover group.

All analyses will be performed using SAS® Version 9.3 or higher.

6.2 Baseline Definition

For analyses of study variables based on the first assigned therapy, baseline is defined as the last measurement obtained prior to the first dose of study drug. For analyses of study variables in the crossover portion, baseline is defined as the last measurement obtained prior to the first dose of KW-0761.

6.3 Determination of Sample Size

Since the primary endpoint is PFS, the reference median PFS for vorinostat is assumed to be 169 days.[5] The median PFS for KW-0761 therapy is targeted for 254 days, a 50% improvement over this reference median. For a 24-month accrual and 12 month follow-up on the last subject dosed, Table 10.3-1 of the protocol gives the power and the number of PFS events required to show superior PFS for KW-0761 therapy over vorinostat at the one-sided

0.025 significance level. The Intent-to-Treat (ITT) set is used for this primary analysis. The same analysis conducted using the Efficacy Evaluable set is considered secondary.

Under these assumptions, for the ITT population, a total of 255 PFS events will give 90% power. For this study, the final primary analysis comparing PFS between treatment groups will not be conducted until 255 PFS events occur or until a maximum of 24 months after the last randomized subject's first dose, whichever comes first. In the event that the study is stopped prior to 255 PFS events being observed, the primary test will be performed at less than 90% power under the current assumptions according to Table 10.3-1 in the protocol.

Each of these calculations used a log-rank test to compare the two survival curves. Sample size calculations were computed using SAS software version 9.3 using PROC POWER, Twosamplesurvival test = logrank.

The total sample size of 288 represents the approximate number of subjects that may be necessary for 255 PFS events to occur within the projected 36 months of the trial. If a 10% inflation factor is applied to this total (about 29 subjects) to take into account those subjects that may be lost to follow-up prior to documented progression, a total of 317 enrolled subjects may be necessary in order to observe 255 PFS events.

The observed rates of PFS events, recruitment, and drop-outs will be monitored throughout the study and may be used to alter the number of sites, the accrual period, and the follow-up period to achieve the required 255 PFS events in a timely manner. If the 255 PFS events are not observed within 36 months from the start of enrollment the study will be stopped at approximately 24 months after the last randomized subject's first dose.

6.4 Analysis Sets

- Intent-to-Treat (ITT) Set: Includes all subjects randomized to a therapy (KW-0761 or vorinostat) and assigned a study number.
- Safety Analysis Set: Includes all subjects who received at least one dose (even a partial dose) of the assigned study agent (KW-0761 or vorinostat).
- Efficacy Evaluable Set: Includes all subjects who receive the first cycle of treatment (at least one dose) and who have baseline tumor assessment and at least one post-baseline assessment for response. If a subject had baseline tumor assessment but progressed (died before progression or had documented progression in follow-up period) during the study without any post-baseline tumor assessment, that subject will still be considered as efficacy evaluable.
- Pharmacokinetic (PK) Analysis Set: All subjects who provide at least one post-dose KW-0761 concentration measurement will be included in the PK analysis set.

6.5 Interim Analysis and Data Monitoring

No formal interim analysis is planned for this study.

A Data Safety Monitoring Board (DSMB) will be responsible for overseeing subject safety in the trial. The DSMB will be comprised of at least two medical doctors and a statistician. A detailed DSMB charter will be developed prior to the safety review.

6.6 Subject Disposition

Subject disposition will be summarized for each treatment arm and in total for all randomized subjects. The following subject disposition categories will be included:

- Subjects who were randomized;
- Subjects who were randomized and did not receive any assigned study drug;
- Subjects who were randomized and treated;
- Subjects who discontinued randomized study drug; and
- Subjects who discontinued from the study.

For subjects who discontinued randomized study drug and subjects who discontinued from the study, a summary of reasons for discontinuation will be provided. The number of subjects in the ITT, Safety Analysis and Efficacy Evaluable Sets will also be summarized.

For subjects who were randomized to vorinostat arm but then cross over into KW-0761 arm, the following disposition categories will be presented for the crossover portion:

- Subjects who were randomized to vorinostat and crossed over to KW-0761;
- Subjects who were crossed over to KW-0761 but did not receive KW-0761;
- Subjects who were crossed over to KW-0761 and received KW-0761;
- Subjects who were crossed over to KW-0761 and discontinued KW-0761; and
- Subjects who were crossed over to KW-0761 and discontinued from the study.

The reasons for discontinuation of KW-0761 and discontinuation from the study during the crossover portion will be provided.

All disposition data will be listed by subject corresponding to their first assigned therapy. A listing will be provided that indicates each subject's inclusion/exclusion from the analysis set and the reason(s) for exclusion from the Efficacy Evaluable Set.

6.7 Demographic and Baseline Disease Characteristics

Demographic and baseline characteristics will be summarized descriptively for the ITT Set, Safety Analysis Set, and the Efficacy Evaluable Set by treatment arm and in total. Gender, race, ethnicity, region, and baseline ECOG performance status will be summarized with contingency tables. Age at screening (years), height, weight, body surface area (BSA), and body mass index (BMI) at baseline will be described with summary statistics (n, mean, standard deviation, median, minimum, and maximum).

Baseline disease characteristics will be collected at screening and will be summarized descriptively for each treatment arm and in total. Time from initial diagnosis (months) will be summarized with descriptive statistics (n, mean, standard deviation, median, minimum, and maximum). Histologically confirmed diagnosis type (MF or SS), clinical stage at diagnosis, current clinical stage, current sites of disease, CCR4 expression status, number of prior CTCL therapies, best response to the last CTCL therapy prior to study entry, and prior radiotherapy will be summarized to show the number and percentage of subjects in each category.

All demographic data and baseline disease characteristics data will be listed by subject.

6.8 Medical and Surgical History

Medical/surgical history will be listed by subject.

6.9 Prior/Concomitant Medications

Prior and concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary (September 2012). Prior medications include medications that were taken within 30 days prior to study entry and stopped prior to start of randomized treatment. Concomitant medications during the randomized treatment period include medications that started at any time and were taken at any time after the start of treatment until the end of the entire randomized treatment period.

The number and percentage of subjects taking concomitant medications during randomized treatment period (excluding crossover) will be summarized by anatomical therapeutic chemical (ATC) and preferred term (PT) for the Safety Analysis Set. Although a subject may have taken two or more medications, the subject is counted only once within an ATC classification. The same subject may contribute to two or more preferred terms in the same classification.

All prior and concomitant medications will be listed by subject. Pruritus medications will also be listed.

6.10 Study Drug Exposure and Compliance

Extent of exposure in days for each subject for the entire randomized treatment period will be calculated as the last dose date of study drug (KW-0761 or vorinostat) minus the first dose date of study drug plus 1. Extent of exposure and total number of cycles initiated during the randomized treatment period will be summarized using descriptive statistics by treatment arm and in total for the Safety Analysis Set. The number and percentage of subjects who initiated treatment for at least 1, 2, 3, 4, 5, and 6 or more cycles will be tabulated by treatment arm and in total.

For the KW-0761 arm, the number of KW-0761 infusions administered, the planned dose (average of the planned dose per subject), the actual dose (average of the actual dose received per subject), and the % dose intensity (total actual dose/total duration of treatment/7) / (total planned dose/total planned weeks) of KW-0761 will be calculated and summarized descriptively. Total planned weeks are based on a 28 day cycle. The following categories of KW-0761 dosing status will be summarized:

- Subjects with total planned dose not administered;
- Subjects with a dose withheld for KW-0761; and
- Subjects with a KW-0761 infusion temporarily interrupted.

In addition, the reasons will be provided for subjects with total planned dose of KW-0761 not administered and for subjects with KW-0761 infusion temporarily interrupted.

For the vorinostat arm, the number and percentage of subjects with dose modifications and the number and percentage of subjects who had non-compliance with dosing for vorinostat will be provided.

For subjects who were randomized to vorinostat arm but then cross over into KW-0761 arm, the extent of exposure to KW-0761 and the total number of cycles initiated during the crossover portion will be summarized. In addition, the number of KW-0761 infusions administered, the % dose intensity, and the dosing status of KW-0761 during the crossover portion will also be summarized descriptively.

All study drug administration data will be listed by subject.

6.11 Efficacy Analysis

Efficacy evaluations will be performed based on both the Intent-to-Treat Set and the Efficacy Evaluable Set.

6.11.1 Efficacy Variables for Analysis

The primary efficacy variable is:

- Progression-free survival (PFS) as assessed by the Investigator

The key secondary efficacy variables are as follows:

- Overall response rate (ORR) as assessed by the Investigator;
- Change in Skindex-29 score from baseline through the 6-month assessment;
- Change in FACT-G total score from baseline through the 6-month assessment;
- Change in EQ-5D-3L index score from baseline through the 6-month assessment.

Other secondary efficacy variables include:

- Progression-free survival (PFS) as assessed by IR;
- Overall response rate (ORR) as assessed by IR;
- Best overall response;
- Duration of response (DOR);
- Time to response (TTR);
- Overall response rate in the crossover portion of the trial;
- Changes from baseline in Skindex-29, FACT-G, and EQ-5D-3L at other timepoints;
- Changes from baseline in Pruritus Evaluation (Likert scale & Itchy QoL).

An overall response is defined as a CR or PR at any time during the treatment period prior to progression/relapse, if applicable. The best overall response is the best response reported across all visits during the treatment period prior to a progression/relapse, if applicable.

The exploratory efficacy variables include:

- Overall survival (OS);
- Time to treatment failure (TTF)

Disease status will be assessed every 4 weeks in skin and blood. In the first year of treatment, response in lymph nodes and viscera and the overall global composite score will be documented every 8 weeks. After the first year, response in the lymph nodes and viscera and the overall global composite score will be documented every 16 weeks. Additionally, if

clinical progression is noted, efficacy assessments are performed to fully document disease progression.

These assessments will be compared with the baseline assessment to determine response. Subjects will be evaluated for response in each compartment and overall. For any time-to-event endpoints (e.g., PFS), the date of disease progression will be determined by both the on-site Investigator's assessment and the IR.

6.11.1.1 Definition of Primary Efficacy Variable

The primary efficacy variable is progression-free survival (PFS) based upon the assessment by the Investigator, defined as the time from the day of randomization to a treatment arm until documented progression or death due to any cause.

Documented disease progression includes disease progression in any compartment based on the Investigator's assessment per CTCL response criteria or documented disease progression reported during the follow-up period. The date of progression will be the earliest date at which documented disease progression can be declared.

For subjects who exhibit conditions of disease progression, but continue on the study due to a questionable clinical impression as described in Section 3.2.2.3, the subject is not considered to have progressed unless disease progression is confirmed at least 4 weeks after the date of the initial questionable disease progression. In this case, the initial date will be used as the date of disease progression.

Subjects who died without a reported prior progression will be considered to have progressed on the day of their death.

The definition of censoring date will be as follows:

- In the event that a randomized subject withdraws from the study for any reason before documented progression, the time from the day of randomization to the last post-baseline tumor assessment from any compartment (skin, blood, bone marrow, lymph node, and viscera) will be used as a censored time point.
- For subjects who are randomized to a treatment arm but have an unknown baseline assessment for a compartment, the PFS time will be censored at the randomization date if there is no post-baseline tumor assessment for that compartment or if there is any evidence of lymphoma in that compartment at post-baseline evaluation.

- For subjects randomized to a treatment arm but withdrawing prior to the first post-baseline tumor assessment for any reason other than disease progression, the PFS time will be censored at the last documented visit.
- For subjects who initiate a new anticancer therapy (including crossover to KW-0761) in the absence of a PFS event, the PFS time will be censored at the last tumor assessment (from any compartment) prior to the start of the new anticancer therapy.
- For subjects not known to have died or have documented progression as of the end of the study, the PFS time will be censored at the date of the last post-baseline tumor assessment (from any compartment).

6.11.1.2 Definition of Key Secondary Efficacy Variables

6.11.1.2.1 Objective Response Rate

The overall response rate (ORR) is defined as the proportion of subjects who are responders (confirmed CR or PR) based on the Investigator's assessment.

Confirmed CR or PR is defined as documented CR or PR based on the Investigator's assessment of overall response per Global Composite Response Score that is subsequently confirmed by two or more consecutive observations for a minimum of 4 weeks. In the case where a subject has visit responses of CR, N/A, CR, then, as long as the time between the 2 visits of CR is greater than 4 weeks, the subject will be defined as a responder.

Subjects lacking valid data to assign a response status will be included in the denominator for response rate calculation based on the ITT Set and, hence, are considered nonresponders.

6.11.1.2.2 Changes in Skindex-29, FACT-G, and EQ-5D-3L from Baseline

The Skindex-29 is a validated instrument to measure the effect of skin disease on health-related quality of life.[6] It is composed of 29 items assessing three domains: emotions, symptoms, and functioning. The items are scored on a 5-point Likert-type scale (never, rarely, sometimes, often, all the time). Responses to each item are transformed to a linear scale of 100 (never=0, rarely=25, sometimes=50, often=75, all the time=100) for the purpose of scale score calculation. A scale score is the mean of a subject's responses to the items in a given scale and the composite Skindex-29 score is calculated as the average of the 3 scale scores to measure the overall impact on quality of life. Higher scores indicate a higher impact of skin disease.

The FACT-G is a validated instrument for assessing health-related quality of life in subjects with cancer.[7] The FACT-G consists of 27 items in the following 4 domains: physical

well-being (PWB), social/family well-being (SWB), emotional well-being (EWB), and functional well-being (FWB). The total FACT-G score is obtained by summing individual subscale scores. Response scores on negatively-phrased questions are reversed before summing. Higher scores for the scales and subscales indicate better quality of life.

The EuroQol/EQ-5D is a standardized, reliable and validated instrument to measure health-related quality of life. The EQ-5D self-reported questionnaire includes the EQ-5D descriptive system and a visual analog scale (VAS). The EQ-5D 3 level version (EQ-5D-3L) descriptive system comprises the following dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems, extreme problems. The EQ-5D index score is calculated based on the descriptive system using a set of item weights (value sets) to derive a single score ranging from -0.109 to 1, with 1 representing full health. The value sets for the US will be used for the calculation of the EQ-5D index score.[8] The EQ-5D self-reported questionnaire also includes a visual analog scale (VAS), which records the respondent's self-rated health status on a graduated (0-100) scale, with 100 = best imaginable health state and 0 = worst imaginable health state.

Skindex-29, FACT-G, and EQ-5D-3L will be evaluated at baseline (Cycle 1 Day 1), end of Cycle 1, then every 8 weeks (i.e., end of Cycle 3, 5, etc), and at the End of Treatment Visit. Measurements at end of cycle 1 are defined as the latest value obtained from Cycle 1 Day 26-28 or Cycle 2 Day 1. Measurements at the end of Cycle x, where x = 3, 5, 7, …, etc, are defined as the latest value obtained from Cycle x Day 26-28, Cycle x Q8 weeks, or Cycle (x+1) Day 1.

The improvement (change from baseline) for each of the quality of life measurements described above will be evaluated at each timepoint as specified in the study procedure tables for each arm.

Missing data for Skindex-29 and FACT-G will be handled according to the questionnaires' scoring guidelines. For Skindex-29, if responses to more than 25% of items are missing overall, the Skindex-29 score will be treated as missing. If any scale has more than 25% of the responses missing, the scale score is missing. The scale scores are the average of the non-missing items in a given scale. For FACT-G, if more than 50% of the items are responded for a subscale, the subscale scores will be prorated by multiplying the sum of the subscale by the number of items in the subscale and then dividing by the number of items actually responded. The total FACT-G score will be scored only if the overall item response rate is greater than 80%. For EQ-5D-3L, the EQ-5D index score will be treated as missing if not all five descriptors are responded.

6.11.1.3 Definition of Other Secondary Efficacy Variables

6.11.1.3.1 Best Overall Response

Best overall response is defined as the best response recorded across all timepoints from the start of treatment until disease progression/recurrence or end of treatment. The subject's best response assignment will depend on the achievement of both measurement and confirmation criteria.

6.11.1.3.2 Duration of Response and Time to Response

Duration of response (DOR) is defined as the time from the date criteria are met for CR/PR (whichever is first recorded) until the first date that PD or death is objectively documented. Subjects who do not relapse will be censored at the day of their last tumor assessment (from any compartment).

Time to response (TTR) is defined as the time from the date of randomization to the date criteria are first met for CR/PR (whichever is first recorded). Subjects who do not respond over the course of the study will have a missing value for TTR.

6.11.1.3.3 Changes in Pruritus Evaluation

Pruritus Evaluation includes the Likert Scale and the Itchy QoL. The Likert scale for pruritus evaluation uses a numbered scale from 0 to 10 to measure the level of itching for pruritus with 10 indicating worst itch imaginable and 0 indicating no itch. The Itchy QoL is a validated pruritus-specific quality of life instrument.[9] It includes 22 pruritus-specific questions covering three major domains: symptoms, functioning, and emotions. The subscale scores consist of the average of the responses to the items in a given subscale. The overall score is the average of the responses to all items. Higher Itchy QoL scores indicate worse quality of life. Missing data in Itchy QoL questionnaire will be handled according to the following rule: if responses to more than 25% of items are missing overall, the overall score will be treated as missing; if any scale has more than 25% of the responses missing, the scale score is missing.

Pruritus Evaluation will be performed at each timepoint specified in the study procedure tables for each arm.

6.11.1.4 Definition of Exploratory Efficacy Variables

6.11.1.4.1 Overall Survival (OS)

Overall survival is defined as the time from the date of randomization until the date of death of the subject due to any cause. Subjects who are still alive at the end of the survival

follow-up period or are lost to follow-up at the time of analysis will be censored on the last date the subject is known to be alive.

6.11.1.4.2 Time to Treatment Failure (TTF)

Time to treatment failure is defined as the time from the day of randomization to a treatment arm until discontinuation of randomized treatment due to any reason except for those subjects who discontinued randomized treatment due to one year on treatment with a CR.

Subjects who experienced an overall CR and discontinued randomized treatment after one year of treatment will be censored at the last dose date of the randomized treatment. Subjects who were randomized but did not take any study drug will be censored at the last documented visit date.

6.11.2 Efficacy Analysis Methodology

6.11.2.1 Analysis of Primary Efficacy Variable

The primary comparison of progression-free survival between KW-0761 and vorinostat will be performed on the ITT set based upon the results of the on-site Investigator's assessment using a stratified Log-rank test at the one-sided 2.5% significance level. Stratification is done by disease type (MF or SS), disease stage (IB/II or III/ IV), and region (U.S., Japan, and Rest of World). A Cox proportional hazard model with treatment, disease type, disease stage, and region (U.S., Japan, and Rest of World) as covariates will be used to assess the magnitude of the treatment difference in PFS. The hazard ratio along with the 95% confidence interval obtained from the Cox proportional hazard model will be presented. Additional analyses may be performed adjusting for treatment and other baseline characteristics.

The median PFS and the 2-sided 95% confidence interval for each treatment will be estimated using the Kaplan-Meier survival analysis methods. Kaplan-Meier estimate of PFS rates and the corresponding 95% confidence interval will also be provided for each treatment arm by 6 months intervals. Plots of the Kaplan-Meier estimate of the survival distribution function over time for PFS will be presented by treatment arm.

The primary analysis of PFS will be performed when 255 total PFS events have been observed or 24 months after the last randomized subject's first dose, whichever comes first.

6.11.2.2 Sensitivity Analyses of Primary Efficacy Variable

Three sensitivity analyses will be performed for PFS during randomized treatment period based on the on-site Investigator's assessment and the ITT Set using the following definitions:

1) Sensitivity Analysis 1: PFS is defined as the time from the day of randomization to a treatment arm until documented progression in any compartment based on the Investigator's assessment per CTCL response criteria or death due to any cause provided that death is not more than 8 weeks after the last post-baseline tumor assessment or the last dose of study drug (if the subject did not have any post-baseline tumor assessment).

   Using this definition, the disease progression reported during the follow-up period would not be considered as an event in the sensitivity analysis, but would be a censored value on the day of the last tumor assessment.

2) Sensitivity Analysis 2: PFS is defined as the time from the day of randomization to a treatment arm until the earliest date of documented progression in any compartment based on the Investigator's assessment per CTCL response criteria, or clinical progression at the end of the randomized treatment, or documented disease progression reported during the follow-up period, or death due to any cause.

   Using this definition, clinical progression noted at the end of the randomized treatment would be considered as an event in the sensitivity analysis.

3) Sensitivity Analysis 3: An additional worst-case sensitivity analysis will be performed based on the ITT Set using the following definition:

   PFS is defined as the time from the day of randomization to a treatment arm until documented progression or death due to any cause. The date of documented disease progression will be the earliest date of disease progression in any compartment based on the Investigator's assessment per CTCL response criteria or disease progression reported during the follow-up period. For assessments where progression is reported by the investigator but is **not** confirmed by the IR, the progression date will be set to the last tumor assessment plus one day in the KW-0761 treatment arm and will be censored in the Vorinostat treatment arm.

The same censoring rules as described in Section 6.11.1.1 will be used for the sensitivity analyses.

6.11.2.3 Analyses of Key Secondary Efficacy Variables

There are four key secondary endpoints in this study that require a comparison between treatment arms: ORR as assessed by the Investigator, changes in Skindex-29 score, FACT-G total score, and EQ-5D-3L index score. All assessments up to 6-months will be of interest for this analysis.

ORR as assessed by the Investigator will be compared between the 2 treatment arms using Cochran-Mantel-Haenszel (CMH) test adjusted for disease type, disease stage, and region. Additional analyses may be performed adjusting for treatment and other baseline characteristics. The exact 95% confidence intervals for ORR will be calculated for each treatment arm along with the difference in response rates between the two treatment arms. All 95% confidence intervals on individual rates will be computed using exact computational methods. Any confidence interval on the difference of proportions will be computed using exact unconditional confidence limits for the risk difference. These confidence intervals can be constructed using SAS® version 9.3 with the FREQ procedure specifying the RISKDIFF option in the EXACT statement.[10] In addition to the results described above, the number and percentage of subjects achieving objective response (CR or PR) will be presented for each treatment arm.

The treatment differences in the mean change of Skindex-29 score from baseline across each planned timepoint (end of cycle 1, cycle 3, cycle 5) up to 6 months of assessments will be tested using a repeated measures mixed effects model with time, region, disease type, disease stage, treatment, and time-by-treatment interaction as factors and baseline score as a covariate. Restricted Maximum Likelihood (REML) method will be used. An unstructured covariance matrix will be employed to model the correlation among repeated measurements. Appropriate contrasts will be used to determine the difference between the Vorinostat treatment group and the KW-0761 treatment group across the end of Cycles 1, 3, and 5. In case of convergence problems, another variance-covariance structure will be considered. The selection of any of these structures will be determined after exploration of the observed correlation structure. Least squares (LS) means, corresponding standard errors, 95% two-sided confidence intervals will be presented for the within-group change for odd cycles. For the between-treatment group comparison, the difference in LS means, corresponding standard errors, 95% two-sided confidence intervals, and two-sided p-value will also be derived from this ANCOVA model and presented for the odd cycles. This mixed-effects model will also be used to compare the treatment differences in the mean changes in Skindex-29 score from baseline to each scheduled time point at end of cycle 1, cycle 3, and cycle 5. In addition to

the Skindex-29 score, a Skindex score based on a subset of Skindex questions may be analyzed in a similar fashion.[11]

Standard model diagnostics will be performed to assess the validity of the proposed ANCOVA model. These diagnostics will include an examination of the residuals for normality and homoscedasticity as well as testing for the significance of the treatment by baseline interaction term. If the residuals are not normally distributed, then the analysis will be carried out using Wilcoxon rank sum test instead.

In addition to the analysis described above, summary statistics including n, mean, standard deviation, median, minimum, and maximum will be provided for Skindex-29 score at baseline and each scheduled time point and change in total score at each of these scheduled assessments for each treatment arm.

The same methods described above for the analysis of change in Skindex-29 score will be performed for the analysis of change from baseline for the ends of cycle 1,3, and 5 in FACT-G total score and EQ-5D-3L index score.

Comparisons of these four key secondary endpoints between the two treatment arms will be conducted using p-values that are adjusted to control the overall study-wise Type 1 error rate to be less than 0.05. The four statistical tests that will be conducted are:

- ORR as assessed by the Investigator,
- Change in Skindex-29 score at through the 6-month assessment,
- Change in FACT-G total score at through the 6-month assessment, and
- Change in EQ-5D-3L index score at through the 6-month assessment.

Since these tests are not independent, the four key secondary tests will be conducted using the Sidak adjusted p-value method defined as:

Adjusted p-value = $1-(1-p)^4$ where **p** is the original p-value of the individual test.

These adjusted p-values will then be compared to .05 for each test.

6.11.2.4 Analyses of Other Secondary Efficacy Variables

Comparisons between treatment arms for all other secondary endpoints such as Pruritus Evaluation (Likert scale and Itchy QoL) will be conducted with no adjustment for multiple comparisons used for those statistical tests.

PFS and ORR as assessed by the IR will be analyzed using the same method described above for PFS and ORR as assessed by the Investigator.

Frequency tables will be used to display the best overall response as assessed by the Investigator and by the IR during the randomized treatment period for all subjects by treatment arm. The concordance between the investigators assessment and the IR assessment of best overall responses will be presented.

For subjects who achieved a confirmed CR or PR during the randomized treatment period, the time to response will be summarized descriptively. The duration of response will be analyzed using survival analysis methods. The Kaplan-Meier estimate of the median duration of response and the associated 95% confidence intervals will be estimated and presented separately for each treatment arm. Because the DOR is a conditional estimate (conditional on having a confirmed response), comparison between KW-0761 and vorinostat would not be based on randomized groups and therefore will not be made.

The same repeated measures ANCOVA model described above for the analysis of change in Skindex-29 score from baseline to end of cycles 1, 3, and 5 will be performed for the changes in Skindex-29 score, FACT-G total score and EQ-5D-3L index score at other time points up to end of cycle 11. Due to the relatively small sample size of subjects after cycle 11, QoL data beyond cycle 11 will only be summarized descriptively. In addition, for EQ-5D-3L descriptive system, frequency tables will be used to display the number and percentage of subjects with reported problems for each level and for each dimension at each scheduled timepoint.

Other quality of life measurements including changes in Pruritus Evaluation (Itchy QoL score) and EQ-5D-3L VAS score from baseline at each scheduled timepoint up to the cycle 11 assessment will also be analyzed using the same method. The assumptions of normality and homogeneity of variance of the ANCOVA analysis will be examined prior to fitting the models. When significant departure from the assumption is observed, the Wilcoxon rank sum test will be applied.

For the Pruritus Evaluation Likert Scale data, the changes in the Likert Scale score from baseline at different timepoints up to the cycle 11 assessments during the randomized treatment period will be analyzed using Wilcoxon rank sum test. The treatment difference in the median change of the Likert Scale score from baseline will be estimated using the Hodges-Lehmann estimate and a two-sided 95% confidence interval for the treatment difference will be obtained using the method of Moses.

All quality of life measurements and changes from baseline will be summarized descriptively at each scheduled time point.

For subjects who cross over from the vorinostat arm to the KW-0761 arm, ORR during the crossover portion of the trial will be estimated in a similar fashion as described above for ORR of the randomized therapy. In addition, the quality of life assessments during the crossover portion will be measured at the end of the first cycle after the first day of dosing for KW-0761. Baseline measurements for the crossover portion are considered to be those taken at the last assessment point of the previous cycle. The quality of life measurements as well as the changes from baseline during the crossover portion of the trial will be summarized descriptively. All summaries for the crossover portion will be purely descriptive. No statistical comparisons will be made for data collected during the crossover portion.

6.11.2.5 Analyses of Exploratory Efficacy Variables

Although not considered a secondary endpoint, a comparison between treatment arms for OS and TTF will be conducted using the same method as described above for the analysis of PFS based on the ITT set and will be considered exploratory.

Additional exploratory analysis will be performed for comparison of PFS between subjects with any exposure to KW-0761 versus subjects with vorinostat only. For this analysis, the PFS for subjects who cross over from the vorinostat arm to KW-0761 will be calculated from the first dose of KW-0761.

Statistical analyses on OS using follow-up data may take place after database lock for the study and will be reported as supplemental to the Clinical Study Report.

The following exploratory analyses will be performed for OS to account for crossover effect:

- The rank-preserving structural failure time (RPSFT) model will be applied to allow a direct comparison of the randomized treatment groups by adjusting the OS of subjects who crossed over so that it reflects the OS had they not received KW-0761. [12]
- The Inverse Probability of Censoring Weighting (IPCW) model will also be applied. In this method subjects who cross over from IC to KW-0761 will be censored and subjects remaining on IC will be weighted to compensate for missing data. The bias introduced by the crossover will be corrected by weighting each subject by the inverse of the predicted probability of not being censored at a given time. [12]

6.11.2.6 Adjustment for Covariates

Additional analysis of the treatment effect on PFS and ORR as assessed by the Investigator when adjusted for potential prognostic factors will be carried out using a multivariate Cox proportional hazard model for PFS and a multivariate logistic regression model for ORR. These analyses will be performed based on the PFS and ORR as assessed by the Investigator for the first assigned therapy and the ITT Set. Potential prognostic factors including disease

type (MF or SS), disease stage (IB and II versus III or IV), compartment involvement (blood involvement or no blood involvement), region (US, Japan, Rest of World), age group (<65 or ≥65 years), gender (males or females), and race category (Black or African American, White, Other) will be included as covariates in the multivariate Cox proportional hazard model for PFS and the multivariate logistic regression model for ORR. Backward selection will be used to identify the final set of prognostic factors (exit p-value is set to be 0.1). The final model will then be used to assess treatment effect when adjusted for these important prognostic factors.

6.11.2.7 Subgroup Analyses

Subgroup analyses will be performed for PFS as assessed by the Investigator based on the first assigned therapy for the ITT Set and the Efficacy Evaluable Set provided that there are adequate sample sizes in the respective groups. The following subgroup factors will be used:

- Disease type (MF or SS);
- Disease stage (IB and II versus III or IV);
- Blood involvement (yes or no);
- Region (US, Japan, Rest of World);
- Age group (<65 years or ≥65 years);
- Gender (male or female);
- Race category (Black or African American, White, Other).
- LDH (normal versus elevated)

Forest plot of hazard ratios by subgroups will be provided for PFS as assessed by the Investigator. Additional subgroup analyses may be performed.

6.12 Safety Analysis

The safety and tolerability of the study drugs are determined by reported AEs, physical examinations, ECGs, vital signs, and laboratory tests. Unless otherwise specified, safety analyses will be based on the safety data collected for the first assigned therapy. For those subjects in the vorinostat arm who cross over to KW-0761 treatment arm, the safety data collected during the crossover portion will be presented separately.

All safety summaries will be based on the entire Safety Analysis Set.

6.12.1 Adverse Events

For subjects in the KW-0761 arm and subjects in the vorinostat arm who do not cross over to KW-0761, treatment-emergent adverse events (TEAEs) during the randomized treatment period are defined as adverse events with an onset date/time after the first dose of randomized study drug until 90 days after the last dose of randomized study drug or initiation of an alternative therapy whichever comes first.

For subjects in the vorinostat arm who cross over to KW-0761 treatment arm, TEAEs during the randomized treatment period are defined as adverse events with an onset date/time after the first dose of randomized study drug and prior to the start of KW-0761. An adverse event with onset date/time after the start of KW-0761 will also be considered as a TEAE during the randomized treatment period if it is considered related to vorinostat. TEAEs during the crossover portion are defined as adverse events with an onset date/time after the first dose of KW-0761 and within 90 days after the last dose of KW-0761 or initiation of an alternative therapy whichever comes first.

TEAEs during the randomized treatment period will be summarized by treatment arm and in total based on the Safety Analysis Set. For subjects who are initially assigned to vorinostat arm and are crossed over to KW-0761 arm, TEAEs during the crossover portion will be summarized separately. A drug-related AE is defined as any event with a relationship to study drug recorded as “definitely”, “probably” or “possibly”. Any adverse events for which relationship to study drug are not recorded will be assumed to be probable.

An overview of adverse events for the randomized treatment period will be provided which summarizes the subject incidence of the following information:

- Any AEs,
- Any TEAEs,
- Drug-related TEAEs,
- NCI/CTCAE grade III/IV/V AEs,
- NCI/CTCAE grade III/IV/V TEAEs,
- Drug-related NCI/CTCAE grade III/IV/V TEAEs,
- Deaths,
- Serious AEs,
- Treatment-emergent SAEs,
- Drug-related treatment-emergent SAEs,
- Discontinuation due to AEs,
- Discontinuation due to TEAEs, and

- Discontinuation due to drug-related TEAEs.

The number and percentage of subjects with TEAEs during the randomized treatment period will be summarized for each treatment arm and in total by system organ class (SOC) and preferred term. Drug-related TEAEs, grade III/IV/V TEAEs, and drug-related grade III/IV/V TEAEs, treatment-emergent SAEs, drug-related treatment-emergent SAEs, TEAEs leading to discontinuation of study drug, and drug-related TEAEs leading to discontinuation of study drug will be summarized in the same manner. For these summaries, subjects with multiple adverse events will be counted only once per SOC and preferred term.

In addition, summaries will be provided for the number and percentage of subjects with TEAEs and drug-related TEAEs by SOC and preferred term and by the highest NCI CTCAE grade. For these summaries, subjects with multiple adverse events will be counted only once by the highest NCI CTCAE grade within an SOC and preferred term.

Adverse events during the crossover portion that are related to KW-0761 will be summarized separately in the same manner as described above for subjects who are randomized to vorinostat arm and then crossed over to KW-0761 treatment. Another summary of adverse events related to Vorinostat may be presented if necessary.

A summary will be provided for the number and percentage of subjects with TEAEs related to KW-0761 by SOC and preferred term for all subjects exposed to KW-0761 and separately for subjects who are initially randomized to KW-0761 and for subjects who are crossed over to KW-0761 treatment.

The number and percentage of subjects with TEAEs during the randomized treatment period will also be summarized for each treatment arm and in total by system organ class (SOC) and preferred term for the following subgroups: Gender and Age (< 65 years vs ≥ 65 years).

In addition to the summaries described above, exposure-adjusted incidence rate and exposure-adjusted event rate will be summarized for each treatment arm and in total by preferred term for the following special TEAEs (system organ class):

- Infections and infestations,
- Respiratory, thoracic and mediastinal disorders,
- Renal and urinary disorders,
- Musculoskelatal and connective tissue disorders.

The exposure-adjusted incidence rate per patient-months of exposure will be calculated as (the number of patients with AEs/sum of days at risk for AEs) * 30.42 days/month; the

exposure-adjusted event rate per patient-months of exposure will be calculated as (the number of AEs/sum of days at risk for AEs) * 30.42 days/month.

Listings will be provided for SAEs, grade III/IV/V AEs, and AEs leading to discontinuation of study drug and AEs leading to death. All adverse events will be listed by subject.

6.12.2 Clinical Laboratory Tests

Local laboratories were used for this study. Shift tables from baseline to the worst post-baseline values during the randomized treatment period according to the NCI-CTCAE v4.0 toxicity grade will be provided for selected chemistry parameters and hematology parameters. The following categories will be used: ≤ Grade II and ≥ Grade III. Both scheduled and unscheduled post-baseline values during the randomized treatment period will be considered. Additionally, the number and percentage of subjects with Grade ≥ III will be presented for the following hematology tests: White Blood Cell Count (WBC), Hemoglobin, Platelet Count and Absolute Neutrophil Count (ANC).

Laboratory data during the crossover portion will be summarized separately in the same manner.

All clinical laboratory data will be listed by subject. Values outside the normal ranges from local laboratories will be flagged and grades will be displayed for selected parameters. Additionally, the laboratory values will display clinical significance based on investigator judgement.

6.12.3 Vital Signs

Vital signs measurements including pulse rate, respiratory rate, temperature, systolic blood pressure, diastolic blood pressure, and body weight will be summarized descriptively (n, mean, standard deviation, median, minimum, and maximum). Baseline and changes from baseline to end of treatment will be presented during the randomized treatment period by treatment arm. Additionally the maximum and minimum post-treatment values during the randomized treatment period will be summarized by treatment arm. Vital signs during the crossover portion will be summarized separately in the same manner.

All vital signs measurements will be listed by subject.

6.12.4 12-Lead Electrocardiogram (ECG)

The QTc intervals are to be determined using the Fridericia correction (QTcF) and the Bazett correction (QTcB). The QTcF and QTcB intervals of the ECG measurements and changes from baseline to end of treatment during the randomized treatment period will be summarized by treatment arm. The number and percentage of subjects with elevated QTcF or QTcB values (> 450 msec, > 480 msec, and > 500 msec) at baseline and end of treatment during the randomized treatment period will be presented by treatment arm. In addition, the number and percentage of subjects with QTcF or QTcB values that increase by > 30 msec and > 60 msec from baseline to end of treatment will also be presented by treatment arm.

A shift table from baseline to the worst post-baseline values during the randomized treatment period will be provided for QTcF and QTcB intervals. The following categories will be used: ≤ 450 msec, > 450 and ≤ 480 msec, > 480 and ≤ 500 msec, and > 500 msec.

All ECG measurements and the overall interpretation will be listed by subject. Abnormal QTcF or QTcB values will be flagged in the listing.

6.12.5 Physical Examinations

Physical examination dates will be listed by subject. Clinically significant findings are recorded as adverse events.

6.12.6 ECOG Performance Status

ECOG performance status mean and mean change from baseline during the randomized treatment period will be tabulated by treatment arm.

All ECOG performance status data will be listed by subject.

6.13 Pharmacokinetics Analysis

Pharmacokinetic (PK) analysis will be conducted using population-based methods. Details of the Pharmacokinetic analysis will be provided in a separate PK analysis plan.

The KW-0761 concentrations at each scheduled time point of collection will be tabulated for subjects in the KW-0761 arm and for subjects who are randomized to vorinostat and crossed over into the KW-0761 arm. If serum KW-0761 concentration is below the lower limit of quantification (BLQ, <1.25 ng/mL), the concentration will be shown as ‘BLQ’ in the data listing, and the data will be considered to be 0 ng/mL when calculating descriptive statistics.

If the mean, minimum, median, or maximum is calculated to be below the lower limit of quantification, it will be shown as 'BLQ' in the summary table. If the mean is below the lower limit of quantification, standard deviation will be shown as '-' in the summary table.

All KW-0761 concentration data will be listed by subject.

6.14 Analysis of Immunogenicity Data

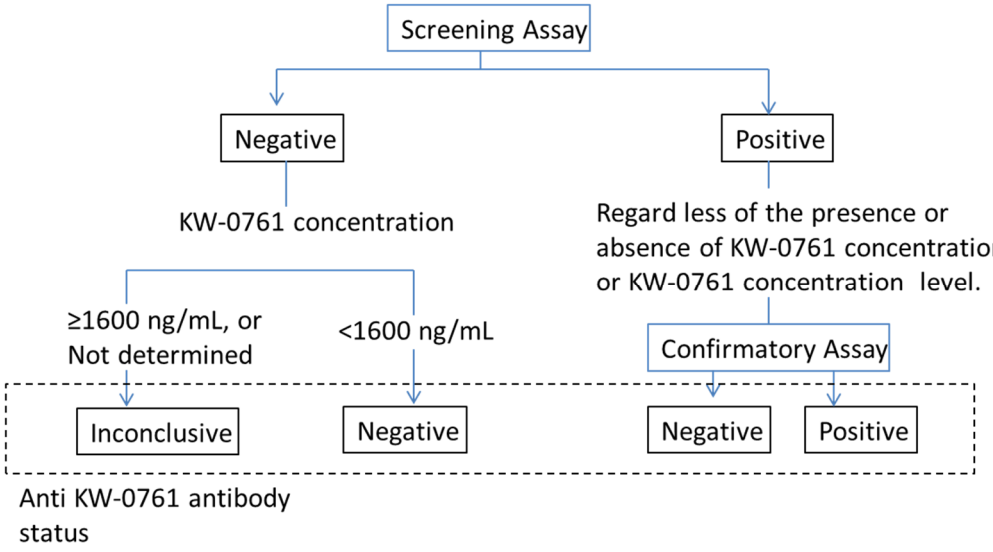
Samples to detect anti-KW-0761 antibodies for the analysis of immunogenicity will be taken at baseline (Cycle 1, Day 1), Day 26-28 of Cycle 1, every 8 weeks thereafter, and at the end of treatment.

Anti-KW-0761 antibody status (positive, negative, and inconclusive) will be tabulated at each scheduled time point and overall at post-baseline for subjects in the KW-0761 arm and separately for those subjects who are randomized to vorinostat but crossed over into the KW-0761 arm. Anti KW-0761 antibody status will be determined using anti-KW-0761 antibody assay result and KW-0761 concentration value as outlined below:

- Positive: When the sample is positive in both screening assay and confirmatory assay, the sample status is considered to be Positive.
- Negative: When the sample is negative in screening assay and KW-0761 concentration at the same time point is equal to or less than drug tolerance limit (16000 ng/mL), or when the sample is positive in screening assay and negative in confirmatory assay, the sample status is considered to be Negative.
- Inconclusive: When the sample is negative in screening assay and KW-0761 concentration at the same time point is above the drug tolerance limit (>16000 ng/mL), the sample status is considered to be Inconclusive. When the sample is negative in screening assay and KW-0761 concentration is not measured, the sample status is considered to be inconclusive.

Anti KW-0761 Antibody Status

-decision tree-



The number and percentage of subjects with a positive neutralizing antibody test result will also be presented for each scheduled time point and overall at post-baseline. For each subject, overall is defined as positive if at least one post-baseline neutralization test result is positive.

Additionally, a summary of subjects with a positive overall assay at any time post-baseline and who experienced infusion reaction will be presented.

All immunogenicity data will be listed by subject.

6.15 Analysis of CCR4 and Other Biomarkers

CCR4 expression results will be listed by subject.

A separate analysis plan will be prepared to detail the CCR4 and other biomarker analyses.

6.16 Other Data Considerations

All other information recorded in the Case Report Form (CRF) (e.g., inclusion and exclusion criteria, natural ligands assessment, genetic determinants (i.e., Fc-gamma receptor polymorphisms), results of serum pregnancy test, etc.) will be listed by subject.

7 REFERENCES

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8 PROGRAMMING CONSIDERATIONS

All tables, data listings, figures (TLFs), and statistical analyses will be generated using SAS® Version 9.3 or higher. Computer-generated table output will adhere to the following specifications.

8.1 Table, Listing, and Figure Format

8.1.1 General

1) All TLFs will be produced in landscape format.
2) All TLFs will be produced using the Courier New font, size 8.
3) The data displays for all TLFs will have a 1.5-inch binding margin on top of a landscape oriented page and a minimum 1-inch margin on the other 3 sides.
4) Headers and footers for figures will be in Courier New font, size 8.
5) Legends will be used for all figures with more than 1 variable, group, or item displayed.
6) TLFs will be in black and white (no color).
7) Specialized text styles, such as bolding, italics, borders, shading, and superscripted and subscripted text, will not be used in the TLFs. On some occasions, superscripts 1, 2, or 3 may be used (see below).
8) Only standard keyboard characters will be used in the TLFs. Special characters, such as non-printable control characters, printer-specific, or font-specific characters, will not be used. Hexadecimal-derived characters will be used, where possible, if they are appropriate to help display math symbols (e.g., μ). Certain superscripts (e.g., cm^2) will be employed on a case-by-case basis.
9) Mixed case will be used for all titles, footnotes, column headers, and programmer-supplied formats.

8.1.2 Headers

1) All output should have the following header at the top of the page:

Kyowa Kirin Pharmaceutical Development, Inc. Date: DD-MMM-YYYY
Study: Protocol 0761-010 Page n of N

All output should have a date (date output was generated) and page number. TLFs should be internally paginated in relation to the total length (i.e., the page number should appear sequentially as page n of N, where N is the total number of pages in the table).

8.1.3 Display Titles

1) Each TLF should be identified by a numeral, and the designation (i.e., Table 1) should be centered above the title. A decimal system (x.y and x.y.z) should be used to identify TLFs with related contents. The title is centered in initial capital characters. The analysis set should be identified on the line immediately following the title. The title and table designation are single spaced. A solid line spanning the margins will separate the display titles from the column headers. There will be 1 blank line between the last title and the solid line.

Table x.y.z
First Line of Title
Second Line of Title if Needed
Safety Analysis Set

8.1.4 Column Headers

1) Column headings should be displayed immediately below the solid line described above in initial upper-case characters. The variable (or characteristic) column will be on the far left followed by the treatment group columns, total column (if applicable), and p-value column (if applicable).
2) For numeric variables, include "unit" in column or row heading when appropriate.
3) Analysis set sizes will be presented for each treatment group in the column heading as (N=xx) (or in the row headings if applicable). This is distinct from the 'n' used for the descriptive statistics representing the number of subjects in the analysis set.
4) The order of treatments in the mock-up tables and listings will be: Vorinostat and KW-0761, and Total (if applicable).

8.1.5 Body of the Data Display

1) Listings will be sorted for presentation in order of treatment groups as above, subject number, collection day, and collection time.
2) If the categories of a parameter are ordered, then all categories between the maximum and minimum category should be presented in the table, even if n=0 for all treatment groups in a given category that is between the minimum and maximum level for that parameter. For example, the frequency distribution for symptom severity would appear as:

Severity Rating	n
severe	0
moderate	8
mild	3

Where percentages are presented in these tables, any counts of 0 will be presented as 0 and not as 0 (0%).

3) If the categories are not ordered (e.g., Medical History, Reasons for Discontinuation from the Study, etc.), then only those categories for which there is at least 1 subject represented in 1 or more groups should be included.
4) An Unknown or Missing category should be added to any parameter for which information is not available for 1 or more subjects.
5) Unless otherwise specified, the estimated mean and median for a set of values should be printed out to 1 more significant digit than the original values, and standard deviations should be printed out to 2 more significant digits than the original values. The minimum and maximum should report the same significant digits as the original values. For example, for systolic blood pressure:

N	XX
Mean	XXX.X
Std Dev	X.XX
Median	XXX.X
Minimum	XXX
Maximum	XXX

6) Data in columns of a table should be formatted as follows:
   - alphanumeric values are left-justified;
   - whole numbers (e.g., counts) are right-justified; and
   - numbers containing fractional portions are decimal aligned.
8) Percentage values should be printed with 1 digit to the right of the decimal point in parentheses 1 space after the count (e.g., 7 (12.8), 13 (5.4)). Less-than-signs "<0.1" should be printed when values are >0.0 and <0.1 (not 0.0). Unless otherwise noted, for all percentages, the number of subjects in the analysis set for the treatment group who have an observation will be the denominator.
9) Tabular display of data for concomitant medications and all tabular displays of adverse event data should be presented by the body system, drug class, or SOC with the highest occurrence in the total column in decreasing order. Within the body system, drug class and SOC, drugs (by ATC1 code) and adverse events (by preferred term) should be displayed in decreasing order. If incidence for more than 1 term is identical, they should then be sorted alphabetically.
10) Missing data should be represented on subject listings as either a hyphen ("-") with a corresponding footnote (" - = unknown or not evaluated"), or as "N/A", with the footnote "N/A = not applicable", whichever is appropriate. Missing descriptive statistics due to non-estimability should be reported as "-".
11) Date should be printed in SAS® YYMMDD10.format ("YYYY-MM-DD": 2000-07-01). Missing portions of dates will not be presented on subject listings (2000-07). Dates that are missing because they are not applicable for the subject are output as "N/A", unless otherwise specified.

12) All observed time values must be presented using a 24-hour clock HH:MM:SS format (e.g., 01:35:45, or 11:26). Time will only be reported if it was measured as part of the study.

8.1.6 Footnotes

1) A solid line spanning the margins will separate the body of the data display from the footnotes.
2) All footnotes will be left justified with single-line spacing immediately below the solid line underneath the data display.
3) Footnotes should always begin with "Note:" if an informational footnote, or asterisks and other non-numeric symbols if an annotated footnote. Each new footnote starts on a new line.
4) Footnotes will be present on the page where they are first referenced and thereafter on each page of the table, unless the footnote is specific only to certain pages. Subject specific footnotes should be avoided.
5) Footnotes will be used sparingly and must add value to the table, figure, or data listing. If more than 4 footnotes are planned, then a cover page may be used to display footnotes, and only those essential to comprehension of the data will be repeated on each page. Footnotes should not repeat definitions already provided in the SAP.
6) The last line of the footnote section will be a standard source line that indicates the data source called in by the program, the name of the program used to produce the data display, and the listing source (i.e., 'Data source: xyzabc.sas7bdat Program source: myprogram.sas Listing source: 16.x.y.z').

8.2 Data-Handling Rules

This section describes naming conventions and rules for calculations that would be common to all applicable tables. Some rules specific to a table can be found in the relevant mock-ups.

8.2.1 Visits

1) Relative Study Day: The first day of treatment is Day 1. A minus (-) sign indicates days prior to the start of treatment (e.g., Day -5 represents 5 days before start of therapy. There is no Day 0.). The relative study day for a specific visit is calculated as (Visit Date - Date of First Dose +1).
2) Baseline: For all study variables, baseline is defined as the last measurement obtained prior to the first dose of the study medication.

8.2.2 Demographics and Baseline Characteristics

1) Age = (Screening visit date - date of birth + 1) / 365.25 and truncated to complete years.

2) BSA (m^2) = ([Height(cm) x Weight(kg)]/ 3600)^{½}
3) BMI (kg/m^2) = Weight(kg) /[Height(m)]^2

8.2.3 Prior and Concomitant Medications

1) Prior and concomitant medications will be coded and classified using the WHO Drug Dictionary (September 2012). The specific dictionary version will be provided in the actual tables/listings.
2) Counting rules for prior and concomitant medications: Prior medications include medications that were taken within 30 days prior to study entry and stopped prior to start of randomized treatment. Concomitant medications during randomized treatment period include medications that started at any time and were taken at any time after the start of randomized treatment until the end of the entire randomized treatment period. Concomitant medications during the crossover portion include medications that started at any time and were taken at any time after the start of KW-0761 during the crossover portion until the end of the entire treatment period.
3) Medications missing both start and stop dates, or having a start date prior to the last dose of study drug and missing the stop date, or having a stop date after the start of study drug and missing the start date, will be counted as concomitant. When partial dates are present in the data, both a partial start date and/or a partial stop date will be evaluated to determine whether it can be conclusively established that the medication either ended prior to the start of study drug or started after the end of study drug. If the above cannot be conclusively established based on the partial and/or present dates, then the medication will be counted as concomitant.

8.2.4 Safety

1) If multiple results (e.g., lab test results) are reported at a study visit, then the most deviant lab result reported for that visit will be used in that visit summary.
2) Adverse events will be coded and classified using the MedDRA dictionary. The specific dictionary version will be provided in the actual tables/listings.
3) Counting rules for adverse events: Adverse events with missing start dates, but with stop dates either overlapping into the treatment period or missing, will be counted as treatment-emergent, taking the worst-case approach. Special care will be taken regarding partial dates with similar logic to that of the prior/concomitant medications applied.
4) For purposes of flagging individual subject data listings, laboratory abnormalities are defined as values above or below the normal range.

8.2.5 SAS® Procedures

This section provides sample SAS® code to illustrate statistical tests specified in the statistical methods section. All computer output from SAS® statistical procedures serving as a basis for extracted results (e.g., LIFETEST) will be retained for quality control procedures and will be included in CSR appendices.

1) Stratified Log Rank test for PFS between treatment:

```
proc lifetest method=KM;
        time PFS*censor(1);
        strata type stage region/group=trt;
run;
```

2) Hazard ratio from Cox proportional hazard model for PFS:

```
proc phreg;
        model PFS*censor(1)=trt type stage region/risklimits ties=efron;
run;
```

3) CMH test for ORR between treatment:

```
proc freq;
        tables type*stage*region*trt*resp/cmh;
run;
```

4) Exact 95% confidence interval on ORR and exact 95% unconditional confidence interval for the risk difference:

```
proc freq;
        tables trt*resp;
        exact riskdiff;
run;
```

5) ANCOVA for change in QoL score between treatment:

```
proc mixed;
        class trt type stage region timept usubjid;
        model QoL_chng = trt type stage region base_QoL timept
                        trt*timept/solution;
        repeated timept / subject=usubjid type=un;
        lsmeans trt/pdiff cl;
run;
```

6) Wilcoxon Rank Sum test for change in Likert Scale score between treatment:

```
proc npar1way wilcoxon hl;
        class trt;
        var QoL_chng;
run;
```

9 LIST OF TABLES AND FIGURES

Disposition, Demographic, Baseline Characteristics, Concomitant Medications, and Exposure and Dosing Status

Efficacy Data

Table 14.2.2.1.2	Logistic Regression Analysis of Confirmed Overall Response Rate (ORR) Based on Investigator's Assessment – Intent-to-Treat Set
Table 14.2.2.1.3	Summary of Confirmed and Unconfirmed Overall Response Rate (ORR) During Randomized Treatment Period – Intent-to-Treat Set
Table 14.2.2.1.4	Summary of Confirmed Overall Response Rate (ORR) During Randomized Treatment Period by Disease Type – Intent-to-Treat Set
Table 14.2.2.1.5	Summary of Confirmed and Unconfirmed Overall Response Rate (ORR) During Randomized Treatment Period by Disease Type – Intent-to-Treat Set
Table 14.2.2.2.1	Summary of Best Overall Response During Randomized Treatment Period – Intent-to-Treat Set
Table 14.2.2.2.2	Summary of Best Overall Response During Randomized Treatment Period by Disease Type – Intent-to-Treat Set
Table 14.2.2.3.1	Summary of Confirmed Overall Response Rate (ORR) During Randomized Treatment Period – Efficacy Evaluable Set
Table 14.2.2.3.2	Summary of Confirmed and Unconfirmed Overall Response Rate (ORR) During Randomized Treatment Period – Efficacy Evaluable Set
Table 14.2.2.3.3	Summary of Confirmed Overall Response Rate (ORR) During Randomized Treatment Period by Disease Type – Efficacy Evaluable Set
Table 14.2.2.3.4	Summary of Confirmed and Unconfirmed Overall Response Rate (ORR) During Randomized Treatment Period by Disease Type – Efficacy Evaluable Set
Table 14.2.2.4.1	Summary of Best Overall Response During Randomized Treatment Period – Efficacy Evaluable Set
Table 14.2.2.4.2	Summary of Best Overall Response During Randomized Treatment Period by Disease Type – Efficacy Evaluable Set
Table 14.2.2.5	Summary of Overall Response During Randomized Treatment Period by Selected Time Points, Investigator's Assessment - Intent-to-Treat Set
Table 14.2.2.6.1	Summary of Duration of Response During Randomized Treatment Period – Intent-to-Treat Set
Table 14.2.2.6.2	Summary of Duration of Response During Randomized Treatment Period by Disease Type – Intent-to-Treat Set
Table 14.2.2.6.3	Summary of Duration of Response During Randomized Treatment Period – Efficacy Evaluable Set
Table 14.2.2.6.4	Summary of Duration of Response During Randomized Treatment Period by Disease Type – Efficacy Evaluable Set
Table 14.2.2.7.1	Summary of Time to Response During Randomized Treatment Period – Intent-to-Treat Set
Table 14.2.2.7.2	Summary of Time to Response During Randomized Treatment Period by Disease Type – Intent-to-Treat Set
Table 14.2.2.7.3	Summary of Time to Response During Randomized Treatment Period – Efficacy Evaluable Set
Table 14.2.2.7.4	Summary of Time to Response During Randomized Treatment Period by Disease Type – Efficacy Evaluable Set
Table 14.2.2.8.1	Summary of Best Overall Response Based on Investigator's Assessment During Crossover Portion – Intent-to-Treat Set – Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761
Table 14.2.2.8.2	Summary of Best Overall Response Based on Investigator's Assessment During

	Crossover Portion by Disease Type – Intent-to-Treat Set – Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761
Table 14.2.2.8.3	Summary of Best Overall Response Based on Investigator's Assessment During Crossover Portion – Efficacy Evaluable Set – Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761
Table 14.2.2.8.4	Summary of Best Overall Response Based on Investigator's Assessment During Crossover Portion by Disease Type – Efficacy Evaluable Set – Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761
Table 14.2.2.9	Concordance Between Independent Review and Investigator's Assessment for Best Overall Response During Randomized Treatment Period – Intent-to-Treat Set
Table 14.2.3.1	Summary of Skindex-29 Score and Change from Baseline by Visit During Randomized Treatment Period – Intent-to-Treat Set
Table 14.2.3.2	Analysis of Change in Skindex-29 Score from Baseline During Randomized Treatment Period – Intent-to-Treat Set
Table 14.2.3.3	Summary of Skindex-29 Score and Change from Baseline by Visit During Randomized Treatment Period – Efficacy Evaluable Set
Table 14.2.3.4	Analysis of Change in Skindex-29 Score from Baseline During Randomized Treatment Period – Efficacy Evaluable Set
Table 14.2.3.5	Summary of Skindex-29 Score and Change from Baseline by Visit During Crossover Portion – Intent-to-Treat Set – Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761
Table 14.2.4.1	Summary of FACT-G Total Score and Change from Baseline by Visit During Randomized Treatment Period – Intent-to-Treat Set
Table 14.2.4.2	Analysis of Change in FACT-G Total Score from Baseline During Randomized Treatment Period – Intent-to-Treat Set
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Table 14.1.1.1
Subject Disposition
Intent-to-Treat Set

	Vorinostat n (%)	KW-0761 n (%)	Total n (%)
Subjects Randomized	xx (100.0)	xx (100.0)	xx (100.0)
Subjects Randomized and Did Not Receive Any Assigned Study Drug	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects Randomized and Treated	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects Discontinued Randomized Study Drug	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study termination by sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progressive disease per CTCL response criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progressive disease - Clinical	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal of consent	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject requires prohibited concomitant medication	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol noncompliance	xx (xx.x)	xx (xx.x)	xx (xx.x)
Investigator decision	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects Randomized to Vorinostat and Crossed Over to KW-0761	xx (xx.x)	-	xx (xx.x)
Subjects Discontinued from the Study	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study termination by sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal of consent	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject did not meet Inc./Exc. criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Analysis Set			
Intent-to-Treat Set	xx (xx.x)	xx (xx.x)	xx (xx.x)
Safety Analysis Set	xx (xx.x)	xx (xx.x)	xx (xx.x)
Efficacy Evaluable Set	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using the number of randomized subjects as the denominator.

Table 14.1.1.2
Subject Disposition – Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

	Total n (%)
Subjects randomized to Vorinostat and crossed over to KW-0761	xx (100.0)
Due to Progression	xx (xx.x)
Due to Intolerance	xx (xx.x)
Subjects who crossed over to KW-0761 but did not receive KW-0761	xx (xx.x)
Subjects who crossed over to KW-0761 and received KW-0761	xx (xx.x)
Subjects crossed over to KW-0761 and discontinued KW-0761	xx (xx.x)
Study termination by sponsor	xx (xx.x)
Progressive disease per CTCL response criteria	xx (xx.x)
Progressive disease - Clinical	xx (xx.x)
Pregnancy	xx (xx.x)
Withdrawal of consent	xx (xx.x)
Subject requires prohibited concomitant medication	xx (xx.x)
Protocol noncompliance	xx (xx.x)
Investigator decision	xx (xx.x)
Adverse event	xx (xx.x)
Death	xx (xx.x)
Other	xx (xx.x)
Subjects crossed over to KW-0761 and discontinued from the study	xx (xx.x)
Study termination by sponsor	xx (xx.x)
Withdrawal of consent	xx (xx.x)
Death	xx (xx.x)
Lost to Follow-up	xx (xx.x)
Subject did not meet Inclusion/Exclusion Criteria	xx (xx.x)
Other	xx (xx.x)

Note: Percentage is calculated using the number of subjects who are randomized to Vorinostat and then crossed over to KW-0761 as the denominator.

Table 14.1.2.1
Demographic and Baseline Disease Characteristics
Intent-to-Treat Set

Variable Statistic/Category	Vorinostat N=xxx	KW-0761 N=xxx	Total N=xxx
Age (years) at Screening			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Minimum	xx	xx	xx
Maximum	xx	xx	xx
Age Group (n, %)			
<65 years	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=65 years	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gender (n, %)			
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race (n, %)			
White	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native American or Alaska Native	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Applicable			
Ethnicity (n, %)			
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Applicable	xx (xx.x)	xx (xx.x)	xx (xx.x)
ECOG Performance Status [1] (n, %)			
0	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of study drug.
* Time from initial diagnosis (months) is calculated as (date of first dose of study medication – date of initial diagnosis + 1)/30. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation.

Table 14.1.2.1
Demographic and Baseline Disease Characteristics
Intent-to-Treat Set

Variable Statistic/Category	Vorinostat N=xxx	KW-0761 N=xxx	Total N=xxx
Region (n, %)			
US	xx (xx.x)	xx (xx.x)	xx (xx.x)
Japan	xx (xx.x)	xx (xx.x)	xx (xx.x)
Rest of World	xx (xx.x)	xx (xx.x)	xx (xx.x)
Height (cm)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Minimum	xx	xx	xx
Maximum	xx	xx	xx
Weight (kg) [1]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Minimum	xx	xx	xx
Maximum	xx	xx	xx
Body Surface Area (m^2) [1]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Minimum	xx	xx	xx
Maximum	xx	xx	xx
Body Mass Index (kg/m^2) [1]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Minimum	xx	xx	xx
Maximum	xx	xx	xx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of study drug.
* Time from initial diagnosis (months) is calculated as (date of first dose of study medication – date of initial diagnosis + 1)/30. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation.

Table 14.1.2.1
Demographic and Baseline Disease Characteristics
Intent-to-Treat Set

Variable Statistic/Category	Vorinostat N=xxx	KW-0761 N=xxx	Total N=xxx
Time from Initial Diagnosis (months)*			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Minimum	xx	xx	xx
Maximum	xx	xx	xx
Disease Type (n, %)			
Mycosis Fungoides (MF)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sézary Syndrome (SS)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Clinical Stage at Diagnosis (n, %)			
IA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IB	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIB	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIIA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIIB	xx (xx.x)	xx (xx.x)	xx (xx.x)
IVA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IVB	xx (xx.x)	xx (xx.x)	xx (xx.x)
I or II	xx (xx.x)	xx (xx.x)	xx (xx.x)
III or IV	xx (xx.x)	xx (xx.x)	xx (xx.x)
Current Clinical Stage (n, %)			
IB	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIB	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIIA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IIIB	xx (xx.x)	xx (xx.x)	xx (xx.x)
IVA	xx (xx.x)	xx (xx.x)	xx (xx.x)
IVB	xx (xx.x)	xx (xx.x)	xx (xx.x)
IB or II	xx (xx.x)	xx (xx.x)	xx (xx.x)
III or IV	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of study drug.
* Time from initial diagnosis (months) is calculated as (date of first dose of study medication – date of initial diagnosis + 1)/30. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation.

Table 14.1.2.1
Demographic and Baseline Disease Characteristics
Intent-to-Treat Set

Variable Statistic/Category	Vorinostat N=xxx	KW-0761 N=xxx	Total N=xxx
Current Sites of Disease (n, %)			
Skin	xx (xx.x)	xx (xx.x)	xx (xx.x)
Nodes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Viscera	xx (xx.x)	xx (xx.x)	xx (xx.x)
Blood	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prior CTCL Therapy (n, %)			
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type of Prior Therapy Received (n, %)			
Bexarotene-Oral	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bexarotene-Topical	xx (xx.x)	xx (xx.x)	xx (xx.x)
Brentuximab Vedotin			
Carmustine	xx (xx.x)	xx (xx.x)	xx (xx.x)
Chlorambucil	xx (xx.x)	xx (xx.x)	xx (xx.x)
Denileukin Diftitox	xx (xx.x)	xx (xx.x)	xx (xx.x)
Doxorubicin HCL Liposome	xx (xx.x)	xx (xx.x)	xx (xx.x)
ECP	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etoposide	xx (xx.x)	xx (xx.x)	xx (xx.x)
IL-12	xx (xx.x)	xx (xx.x)	xx (xx.x)
Interferon-α	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pralatrexate	xx (xx.x)	xx (xx.x)	xx (xx.x)
Methotrexate	xx (xx.x)	xx (xx.x)	xx (xx.x)
Nitrogen Mustard	xx (xx.x)	xx (xx.x)	xx (xx.x)
PUVA	xx (xx.x)	xx (xx.x)	xx (xx.x)
Romidepsin	xx (xx.x)	xx (xx.x)	xx (xx.x)
Topical Steroid	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of study drug.
* Time from initial diagnosis (months) is calculated as (date of first dose of study medication – date of initial diagnosis + 1)/30. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation.

Table 14.1.2.1
Demographic and Baseline Disease Characteristics
Intent-to-Treat Set

Variable Statistic/Category	Vorinostat N=xxx	KW-0761 N=xxx	Total N=xxx
Prior CTCL Therapy			
Number of Prior CTCL Therapies (n, %)			
1	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	xx (xx.x)	xx (xx.x)	xx (xx.x)
5	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=6	xx (xx.x)	xx (xx.x)	xx (xx.x)
Best Response to Last CTCL Therapy Prior to Study Entry (n, %)			
Complete response	xx (xx.x)	xx (xx.x)	xx (xx.x)
Partial response	xx (xx.x)	xx (xx.x)	xx (xx.x)
Complete response or partial response	xx (xx.x)	xx (xx.x)	xx (xx.x)
Stable disease	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progressive disease	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not applicable	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prior Radiotherapy (n, %)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
CCR4 Expression Status (n, %)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Positive	xx (xx.x)	xx (xx.x)	xx (xx.x)
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of study drug.
* Time from initial diagnosis (months) is calculated as (date of first dose of study medication – date of initial diagnosis + 1)/30. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation.

Table 14.1.2.1
Demographic and Baseline Disease Characteristics
Intent-to-Treat Set

Variable Statistic/Category	Vorinostat N=xxx	KW-0761 N=xxx	Total N=xxx
LDH (U/L) at Baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Minimum	xx	xx	xx
Maximum	xx	xx	xx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Baseline is defined as the last measurement obtained prior to the first dose of study drug.
* Time from initial diagnosis (months) is calculated as (date of first dose of study medication – date of initial diagnosis + 1)/30. If the month and year of the diagnosis are provided but the day is missing, the missing day is imputed as 15. If only the year is provided, then the missing month and day are imputed as July 1 for the calculation.

The following tables will have a similar layout as Table 14.1.2.1:

Table 14.1.2.2
Demographic and Baseline Disease Characteristics
Safety Analysis Set

Table 14.1.2.3
Demographic and Baseline Disease Characteristics
Efficacy Evaluable Set

Table 14.1.3
Summary of Concomitant Medications During Randomized Treatment Period – Number (%) of Subjects
Safety Analysis Set

ATC Classification Preferred Term	Vorinostat N=xxx n (%)	KW-0761 N=xxx n (%)
Total	xx (xx.x)	xx (xx.x)
ATC Classification 1	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)
	xx (xx.x)	xx (xx.x)
ATC Classification 1		
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
Medications that started at any time and were taken at any time after the start of treatment until the end of the entire randomized treatment period are included.

Table 14.1.4
Summary of Extent of Exposure to Randomized Study Drug
Safety Analysis Set

	Vorinostat N=xxx	KW-0761 N=xxx
Extent of Exposure (Days)		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx
Number of KW-0761 Infusions Administered		
n		xx
Mean		xx.x
Std Dev		xx.xx
Median		xx.x
Minimum		xx
Maximum		xx
Total Number of Cycles Initiated		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx
Subjects Who Initiated Treatment for at Least*		
1 Cycle	xx (xx.x)	xx (xx.x)
2 Cycles	xx (xx.x)	xx (xx.x)
3 Cycles	xx (xx.x)	xx (xx.x)
4 Cycles	xx (xx.x)	xx (xx.x)
5 Cycles	xx (xx.x)	xx (xx.x)
6 Cycles	xx (xx.x)	xx (xx.x)
Etc.		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* A subject is considered initiated treatment for a cycle if the subject received any assigned study drug for that cycle.
** % dose intensity is calculated as 100*(total actual dose/total duration of treatment/7)/(total planned dose/total planned weeks).

Table 14.1.4
Summary of Extent of Exposure to Randomized Study Drug
Safety Analysis Set

	Vorinostat N=xx	KW-0761 N=xx
Average Planned Dose of KW-0761 (mg)		
n		xx
Mean		xx.x
Std Dev		xx.xx
Median		xx.x
Minimum		xx
Maximum		xx
Average Actual Dose of KW-0761 (mg)		
n		xx
Mean		xx.x
Std Dev		xx.xx
Median		xx.x
Minimum		xx
Maximum		xx
% Dose Intensity of KW-0761**		
n		xx
Mean		xx.x
Std Dev		xx.xx
Median		xx.x
Minimum		xx
Maximum		xx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* A subject is considered initiated treatment for a cycle if the subject received any assigned study drug for that cycle.
** % dose intensity is calculated as 100*(total actual dose/total duration of treatment/7)/(total planned dose/total planned weeks).

Table 14.1.5
Summary of Study Drug Dosing Status During Randomized Treatment Period
Safety Analysis Set

	Vorinostat N=xx n (%)	KW-0761 N=xx n (%)
Subjects with a Dose Withheld for KW-0761		xx (xx.x)
Subjects with Total Planned Dose of KW-0761 Not Administered		xx (xx.x)
Reason:		
Infusion reaction		xx (xx.x)
Other adverse event		xx (xx.x)
Mechanical equipment issue		xx (xx.x)
Other		xx (xx.x)
Subjects with a KW-0761 Infusion Temporarily Interrupted		xx (xx.x)
Reason:		
Infusion reaction		xx (xx.x)
Other adverse event		xx (xx.x)
Mechanical equipment issue		xx (xx.x)
Other		xx (xx.x)
Subjects with Dose Modifications for Vorinostat	xx (xx.x)	
Subjects with Non-compliance with Dosing for Vorinostat*	xx (xx.x)	

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* Non-compliance is based on investigator assessment.

The following tables will have similar layout as Table 14.1.4 and Table 14.1.5:

Table 14.1.6
Summary of Extent of Exposure to KW-0761 During Crossover Portion
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.1.7
Summary of KW-0761 Dosing Status During Crossover Portion
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.2.1.1
Summary of Progression-Free Survival (PFS) Based on Investigator's Assessment
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
Number of Subjects with PFS Event (n, %)	xx (xx.x)	xx (xx.x)
Earliest Contributing Event:		
Progressive Disease	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)
Number of Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Progression-Free Survival (months)		
Kaplan-Meier Estimate of PFS		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat**		
Hazard Ratio (95% CI)		xx.x (xx.x, xx.x)
Log rank p-value		x.xxxx
Rate (%) of Being Alive without Progression for at Least***		
6 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
12 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
18 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
24 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Etc.		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.
** Hazard ratio and 95% CI are based on Cox proportional hazards model with treatment, disease type, disease stage, and region as covariates. P-value (two-sided) is obtained from a stratified log rank test (one-sided test at 0.025 level or equivalently two-sided test at 0.05 level) with disease type, disease stage, and region as stratification factors.
*** Kaplan-Meier estimate.

The following tables will have similar layout as Table 14.2.1.1:

Table 14.2.1.2
Summary of Progression-Free Survival (PFS) Based on Investigator's Assessment
Sensitivity Analysis 1
Intent-to-Treat Set

Table 14.2.1.3
Summary of Progression-Free Survival (PFS) Based on Investigator's Assessment
Sensitivity Analysis 2
Intent-to-Treat Set

Table 14.2.1.4
Summary of Progression-Free Survival (PFS) Based on Investigator's Assessment – Worst Case Sensitivity Analysis
Sensitivity Analysis 3
Intent-to-Treat Set

<<Programming Note: Add the corresponding PFS definition in the footnote for Tables 14.2.1.2 to 14.2.1.4 per SAP Section 6.11.2.2.>>

Table 14.2.1.5
Multivariate Analysis of Progression-Free Survival (PFS) Based on Investigator's Assessment
Intent-to-Treat Set

Prognostic Factors	Progression-Free Survival (Months) Hazard Ratio (95% CI)	P-value
Treatment		
KW-0761 vs. Vorinostat	xx.x (xx.x, xx.x)	x.xxxx
Disease Type		
MF vs. SS	xx.x (xx.x, xx.x)	x.xxxx
Disease Stage		
IB/II vs. III/IV	xx.x (xx.x, xx.x)	x.xxxx
Blood Involvement		
Yes vs. No	xx.x (xx.x, xx.x)	x.xxxx
Region		
US vs. Japan	xx.x (xx.x, xx.x)	x.xxxx
US vs. Rest of World	xx.x (xx.x, xx.x)	x.xxxx
Japan vs Rest of World	xx.x (xx.x, xx.x)	x.xxxx
Age Group		
>=65 vs. <65 yrs	xx.x (xx.x, xx.x)	x.xxxx
Gender		
Male vs. female	xx.x (xx.x, xx.x)	x.xxxx
Race Category		
White vs. Black or African American	xx.x (xx.x, xx.x)	x.xxxx
White vs. Other	xx.x (xx.x, xx.x)	x.xxxx

Note: Hazard ratio, 95% CI, and p-value are obtained from a Cox proportional hazard model with treatment, disease type, disease stage, Blood Involvement, region, age group, gender, and race category as explanatory variables.

<<Programming Note: Backward selection method will be used to identify the final set of prognostic factors (exit p-value is set to be 0.1). Treatment will be fixed in the model, i.e., will not be eliminated.>>

The following table will have a similar layout as Table 14.2.1.1:

Table 14.2.1.6.1
Summary of Progression-Free Survival (PFS)
Efficacy Evaluable Set

Table 14.2.1.6.2
Summary of Progression-Free Survival (PFS)
Intent-to-Treat Set
Any Exposure to KW-0761 vs. Vorinostat Only

		KW-0761#		
	Vorinostat N=xxx	Crossover	Randomized to KW-0761 N=xxx	Any KW-0761
By Investigator's Assessment				
Number of Subjects with PFS Event (n, %)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Earliest Contributing Event:				
Progressive Disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progression-Free Survival (months)				
Kaplan-Meier Estimate of PFS				
Q1	xx.x	xx.x	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x	xx.x	xx.x
Mean	xx.xx	xx.xx	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx
Minimum	xx.x	xx.x	xx.x	xx.x
Maximum	xx.x	xx.x	xx.x	xx.x
------ Treatment Comparison ------				
KW-0761 vs. Vorinostat**				
Hazard Ratio (95% CI)				xx.x (xx.x, xx.x)
Log rank p-value				x.xxxx
Rate (%) of Being Alive without Progression for at Least***				
6 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
12 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
18 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
24 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Etc.				

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.
** Hazard ratio and 95% CI are based on Cox proportional hazards model with treatment, disease type, disease stage, and region as covariates. P-value (two-sided) is obtained from a stratified log rank test (one-sided test at 0.025 level or equivalently two-sided test at 0.05 level) with disease type, disease stage, and region as stratification factors.
*** Kaplan-Meier estimate.
# For subjects who had KW-0761 treatment, PFS is calculated from the first dose of KW-0761.

Table 14.2.1.6.2
Summary of Progression-Free Survival (PFS)
Intent-to-Treat Set
Any Exposure to KW-0761 vs. Vorinostat Only

		KW-0761#		
	Vorinostat N=xxx	Crossover	Randomized to KW-0761 N=xxx	Any KW-0761
By Independent Review Committee				
Number of Subjects with PFS Event (n, %)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Earliest Contributing Event:				
Progressive Disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progression-Free Survival (months)				
Kaplan-Meier Estimate of PFS				
Q1	xx.x	xx.x	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x	xx.x	xx.x
Mean	xx.xx	xx.xx	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median	xx.xx	xx.xx	xx.xx	xx.xx
Minimum	xx.x	xx.x	xx.x	xx.x
Maximum	xx.x	xx.x	xx.x	xx.x
------ Treatment Comparison ------				
KW-0761 vs. Vorinostat**				
Hazard Ratio (95% CI)				xx.x (xx.x, xx.x)
Log rank p-value				x.xxxx
Rate (%) of Being Alive without Progression for at Least***				
6 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
12 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
18 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
24 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Etc.				

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.
** Hazard ratio and 95% CI are based on Cox proportional hazards model with treatment, disease type, disease stage, and region as covariates. P-value (two-sided) is obtained from a stratified log rank test (one-sided test at 0.025 level or equivalently two-sided test at 0.05 level) with disease type, disease stage, and region as stratification factors.
*** Kaplan-Meier estimate.
# For subjects who had KW-0761 treatment, PFS is calculated from the first dose of KW-0761.

Table 14.2.1.7.1
Summary of Progression-Free Survival (PFS) Based on Investigator's Assessment
Intent-to-Treat Set
By Pre-defined Subgroups

Disease Type = MF

	Vorinostat N=xxx	KW-0761 N=xxx
Number of Subjects with PFS Event (n, %)	xx (xx.x)	xx (xx.x)
Earliest Contributing Event:		
Progressive Disease	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)
Number of Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Progression-Free Survival (months)		
Kaplan-Meier Estimate of PFS		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat**		
Hazard Ratio (95% CI)		xx.x (xx.x, xx.x)
Log rank p-value		x.xxxx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.
** Hazard ratio and 95% CI are based on Cox proportional hazards model with treatment, disease stage, and region as covariates. P-value is obtained from a stratified log rank test with disease stage and region as stratification factors.

<<Programming Note: Repeat for the following subgroups: Disease Type (SS), Disease Stage, Blood Involvement, Region, Age group, Gender, Race Category, and Baseline LDH.>>

The following table will have a similar layout as Table 14.2.1.7.1:

Table 14.2.1.7.2
Summary of Progression-Free Survival (PFS) Based on Investigator's Assessment
Efficacy Evaluable Set
By Pre-defined Subgroups

Table 14.2.1.8
Summary of Progression-Free Survival (PFS) Based on Independent Review
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
Number of Subjects with PFS Event (n, %)	xx (xx.x)	xx (xx.x)
Earliest Contributing Event:		
Progressive Disease	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)
Number of Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Progression-Free Survival (months)		
Kaplan-Meier Estimate of PFS		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat**		
Hazard Ratio (95% CI)		xx.x (xx.x, xx.x)
Log rank p-value		x.xxxx
Rate (%) of Being Alive without Progression for at Least***		
6 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
12 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
18 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
24 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Etc.		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.
** Hazard ratio and 95% CI are based on Cox proportional hazards model with treatment, disease type, disease stage, and region as covariates. P-value (two-sided) is obtained from a stratified log rank test (one-sided test at 0.025 level or equivalently two-sided test at 0.05 level) with disease type disease stage, and region as stratification factors.
*** Kaplan-Meier estimate.

Table 14.2.2.1.1
Summary of Confirmed Overall Response Rate (ORR) During Randomized Treatment Period
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
By Investigator's Assessment		
Overall response rate (confirmed CR + PR) (n, %)	xx (xx.x)	xx (xx.x)
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat		
Risk Diff		xx.x
95% CI*		(xx.x, xx.x)
P-value**		x.xxxx
Adjusted P-value**		x.xxxx
By Independent Review Committee		
Overall response rate (confirmed CR + PR) (n, %)	xx (xx.x)	xx (xx.x)
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat		
Risk Diff	xx.x	xx.x
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
P-value**		x.xxxx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. CR = complete response, PR = partial response.
Overall Response Rate is based on Global Composite Response Score.
* 95% CI for response rate is the exact 95% confidence interval. 95% CI for difference is the exact 95% unconditional confidence interval for the risk difference (KW-0761 – Vorinostat).
** P-value is obtained from Cochran-Mantel-Haenszel test adjusting for disease type, disease stage, and region. Adjusted P-value is calculated using Sidak method.

Table 14.2.2.1.2
Logistic Regression Analysis of Confirmed Overall Response Rate (ORR) During Randomized Treatment Period
Based on Investigator's Assessment
Intent-to-Treat Set

Prognostic Factor	Odds Ratio Estimate (SE)	95% CI	P-value
Treatment			
KW-0761 vs. Vorinostat	xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Disease Type			
MF vs. SS	xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Disease Stage			
IB/II vs. III/IV	xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Blood Involvement			
Yes vs. No	xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Region			
US vs. Japan			
US vs. Rest of World			
Japan vs Rest of World	xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Age Group			
>=65 vs. <65 years old	xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Gender			
Male vs. female	xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Race Category			
White vs. Black or African America	xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
White vs. Other	xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx

Note: Odds ratio, SE, 95% CI, and p-value are obtained from a multivariate logistic regression model with treatment, disease type, disease stage, blood Involvement, region, age group, gender, and race category as explanatory variables.
Overall Response is based on Global Composite Response Score.

<<Programming Note: Backward selection method will be used to identify the final set of prognostic factors (exit p-value is set to be 0.1). Treatment will be fixed in the model, i.e., will not be eliminated.>>

Table 14.2.2.1.3

Summary of Confirmed and Unconfirmed Overall Response Rate (ORR) During Randomized Treatment Period
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
By Investigator's Assessment		
Overall response rate (confirmed and unconfirmed CR + PR) (n, %)	xx (xx.x)	xx (xx.x)
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat		
Risk Diff		xx.x
95% CI*		(xx.x, xx.x)
P-value**		x.xxxx
By Independent Review Committee		
Overall response rate (confirmed and unconfirmed CR + PR) (n, %)	xx (xx.x)	xx (xx.x)
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat		
Risk Diff	xx.x	xx.x
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
P-value**		x.xxxx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. CR = complete response, PR = partial response.
Overall Response Rate is based on Global Composite Response Score.
* 95% CI for response rate is the exact 95% confidence interval. 95% CI for difference is the exact 95% unconditional confidence interval for the risk difference (KW-0761 – Vorinostat).
** P-value is obtained from Cochran-Mantel-Haenszel test adjusting for disease type, disease stage, and region.

Table 14.2.2.1.4
Summary of Confirmed Overall Response Rate (ORR) During Randomized Treatment Period by Disease Type
Intent-to-Treat Set

Disease Type = MF

	Vorinostat N=xxx	KW-0761 N=xxx
By Investigator's Assessment		
Overall response rate (confirmed CR + PR) (n, %)	xx (xx.x)	xx (xx.x)
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat		
Risk Diff		xx.x
95% CI*		(xx.x, xx.x)
P-value**		x.xxxx
Adjusted P-value**		x.xxxx
By Independent Review Committee		
Overall response rate (confirmed CR + PR) (n, %)	xx (xx.x)	xx (xx.x)
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat		
Risk Diff	xx.x	xx.x
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
P-value**		x.xxxx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. CR = complete response, PR = partial response.
Overall Response Rate is based on Global Composite Response Score.
* 95% CI for response rate is the exact 95% confidence interval. 95% CI for difference is the exact 95% unconditional confidence interval for the risk difference (KW-0761 – Vorinostat).
** P-value is obtained from Cochran-Mantel-Haenszel test adjusting for disease type, disease stage, and region. Adjusted P-value is calculated using Sidak method.

<<Programming Note: Repeat for the following subgroup: Disease Type (SS).>>

Table 14.2.2.1.5
Summary of Confirmed and Unconfirmed Overall Response Rate (ORR) During Randomized Treatment Period by Disease Type
Intent-to-Treat Set

Disease Type = MF

	Vorinostat N=xxx	KW-0761 N=xxx
By Investigator's Assessment		
Overall response rate (confirmed and unconfirmed CR + PR) (n, %)	xx (xx.x)	xx (xx.x)
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat		
Risk Diff		xx.x
95% CI*		(xx.x, xx.x)
P-value**		x.xxxx
By Independent Review Committee		
Overall response rate (confirmed and unconfirmed CR + PR) (n, %)	xx (xx.x)	xx (xx.x)
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
------ Treatment Comparison ------		
KW-0761 vs. Vorinostat		
Risk Diff	xx.x	xx.x
95% CI*	(xx.x, xx.x)	(xx.x, xx.x)
P-value**		x.xxxx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. CR = complete response, PR = partial response.
Overall Response Rate is based on Global Composite Response Score.
* 95% CI for response rate is the exact 95% confidence interval. 95% CI for difference is the exact 95% unconditional confidence interval for the risk difference (KW-0761 – Vorinostat).
** P-value is obtained from Cochran-Mantel-Haenszel test adjusting for disease type, disease stage, and region.

<<Programming Note: Repeat for the following subgroup: Disease Type (SS).>>

Table 14.2.2.2.1
Summary of Best Overall Response During Randomized Treatment Period
Intent-to-Treat Set

Best Overall Response	Vorinostat N=xxx n (%)	KW-0761 N=xxx n (%)
By Investigator's Assessment		
Responders (CR + PR)	xx (xx.x)	xx (xx.x)
Complete response(CR)	xx (xx.x)	xx (xx.x)
Confirmed CR	xx (xx.x)	xx (xx.x)
Partial response (PR)	xx (xx.x)	xx (xx.x)
Confirmed PR	xx (xx.x)	xx (xx.x)
Stable disease	xx (xx.x)	xx (xx.x)
Progressive disease	xx (xx.x)	xx (xx.x)
Not Assessable*	xx (xx.x)	xx (xx.x)
Clinical Progression		
By Independent Review Committee		
Responders (CR + PR)	xx (xx.x)	xx (xx.x)
Complete response (CR)	xx (xx.x)	xx (xx.x)
Confirmed CR	xx (xx.x)	xx (xx.x)
Partial response (PR)	xx (xx.x)	xx (xx.x)
Confirmed PR	xx (xx.x)	xx (xx.x)
Stable disease	xx (xx.x)	xx (xx.x)
Progressive disease	xx (xx.x)	xx (xx.x)
Not Assessable*	xx (xx.x)	xx (xx.x)
Clinical Progression		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
Overall Response is based on Global Composite Response Score.
* If there is no post-baseline tumor assessment or the response for all post-baseline tumor assessments is not assessable or unable to evaluate, the best overall response is classified as not assessable.

Table 14.2.2.2.2
Summary of Best Overall Response During Randomized Treatment Period by Disease Type
Intent-to-Treat Set

Disease Type = MF

Best Overall Response	Vorinostat N=xxx n (%)	KW-0761 N=xxx n (%)
By Investigator's Assessment		
Complete response(CR)	xx (xx.x)	xx (xx.x)
Confirmed CR	xx (xx.x)	xx (xx.x)
Partial response (PR)	xx (xx.x)	xx (xx.x)
Confirmed PR	xx (xx.x)	xx (xx.x)
Stable disease	xx (xx.x)	xx (xx.x)
Progressive disease	xx (xx.x)	xx (xx.x)
Not Assessable*	xx (xx.x)	xx (xx.x)
Clinical Progression		
By Independent Review Committee		
Complete response (CR)	xx (xx.x)	xx (xx.x)
Confirmed CR	xx (xx.x)	xx (xx.x)
Partial response (PR)	xx (xx.x)	xx (xx.x)
Confirmed PR	xx (xx.x)	xx (xx.x)
Stable disease	xx (xx.x)	xx (xx.x)
Progressive disease	xx (xx.x)	xx (xx.x)
Not Assessable*	xx (xx.x)	xx (xx.x)
Clinical Progression		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* If there is no post-baseline tumor assessment or the response for all post-baseline tumor assessments is not assessable or unable to evaluate, the best overall response is classified as not assessable.

<<Programming Note: Repeat for the following subgroup: Disease Type (SS).>>

The following tables will have similar layouts as Tables 14.2.2.1.1, 14.2.2.1.3, 14.2.2.1.4, 14.2.2.1.5 except the p-values will be removed.

Table 14.2.2.3.1
Summary of Confirmed Overall Response Rate (ORR) During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.2.3.2
Summary of Confirmed and Unconfirmed Overall Response Rate (ORR) During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.2.3.3
Summary of Confirmed Overall Response Rate (ORR) During Randomized Treatment Period by Disease Type
Efficacy Evaluable Set

Table 14.2.2.3
Summary of Confirmed and Unconfirmed Overall Response Rate (ORR) During Randomized Treatment Period by Disease Type
Efficacy Evaluable Set

The following tables will have similar layout as Tables 14.2.2.2.1 and 14.2.2.2.2.

Table 14.2.2.4.1
Summary of Best Overall Response During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.2.4.2
Summary of Best Overall Response During Randomized Treatment Period by Disease Type
Efficacy Evaluable Set

Table 14.2.2.5
Summary of Overall Response During Randomized Treatment Period by Selected Time Points
Investigator's Assessment
Intent-to-Treat Set

Overall Response	Vorinostat N=xxx n (%)	KW-0761 N=xxx n (%)
End of Cycle 3		
Complete response(CR)	xx (xx.x)	xx (xx.x)
Partial response (PR)	xx (xx.x)	xx (xx.x)
Stable disease	xx (xx.x)	xx (xx.x)
Progressive disease	xx (xx.x)	xx (xx.x)
Not Assessable*	xx (xx.x)	xx (xx.x)
End of Cycle 5		
Complete response(CR)	xx (xx.x)	xx (xx.x)
Partial response (PR)	xx (xx.x)	xx (xx.x)
Stable disease	xx (xx.x)	xx (xx.x)
Progressive disease	xx (xx.x)	xx (xx.x)
Not Assessable*	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* If there is no post-baseline tumor assessment or the response for all post-baseline tumor assessments is not assessable or unable to evaluate, the best overall response is classified as not assessable.

<<Programming Note: Repeat for Cycles 7, 11, 13, 25).>>

Table 14.2.2.6.1
Summary of Duration of Response During Randomized Treatment Period
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
By Investigator's Assessment		
Number of Subjects with Confirmed CR or PR	N'=xx	N'=xx
Subjects with Progressive Disease (n, %)	xx (xx.x)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Duration of Response (months)		
Kaplan-Meier Estimate		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x
By Independent Review Committee		
Number of Subjects with Confirmed CR or PR	N'=xx	N'=xx
Subjects with Progressive Disease (n, %)	xx (xx.x)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Duration of Response (months)		
Kaplan-Meier Estimate		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x

Note: Percentage is calculated using N' as the denominator. CR = complete response, PR = partial response.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.

Table 14.2.2.6.2
Summary of Duration of Response During Randomized Treatment Period by Disease Type
Intent-to-Treat Set

Disease Type = MF

	Vorinostat N=xxx	KW-0761 N=xxx
By Investigator's Assessment		
Number of Subjects with Confirmed CR or PR	N'=xx	N'=xx
Subjects with Progressive Disease (n, %)	xx (xx.x)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Duration of Response (months)		
Kaplan-Meier Estimate		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x
By Independent Review Committee		
Number of Subjects with Confirmed CR or PR	N'=xx	N'=xx
Subjects with Progressive Disease (n, %)	xx (xx.x)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Duration of Response (months)		
Kaplan-Meier Estimate		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x

Note: Percentage is calculated using N' as the denominator. CR = complete response, PR = partial response.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.

<<Programming Note: Repeat for the following subgroup: Disease Type (SS).>>

The following tables will have a similar layout as Table 14.2.2.6.1 and 14.2.2.6.2:

Table 14.2.2.6.3
Summary of Duration of Response During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.2.6.4
Summary of Duration of Response During Randomized Treatment Period by Disease Type
Efficacy Evaluable Set

Table 14.2.2.7.1
Summary of Time to Response During Randomized Treatment Period
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
By Investigator's Assessment		
Time to Response (months)*		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx
By Independent Review Committee		
Time to Response (months)*		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx

* For subjects with confirmed complete response or partial response.

Table 14.2.2.7.2
Summary of Time to Response During Randomized Treatment Period by Disease Type
Intent-to-Treat Set

Disease Type = MF

	Vorinostat N=xxx	KW-0761 N=xxx
By Investigator's Assessment		
Time to Response (months)*		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx
By Independent Review Committee		
Time to Response (months)*		
n	xx	xx
Mean	xx.x	xx.x
Std Dev	xx.xx	xx.xx
Median	xx.x	xx.x
Minimum	xx	xx
Maximum	xx	xx

* For subjects with confirmed complete response or partial response.

<<Programming Note: Repeat for the following subgroup: Histologically Confirmed Diagnosis (SS).>>

The following tables will have a similar layout as Table 14.2.2.7.1 and 14.2.2.7.2:

Table 14.2.2.7.3
Summary of Time to Response During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.2.7.4
Summary of Time to Response During Randomized Treatment Period by Disease Type
Efficacy Evaluable Set

Table 14.2.2.8.1
Summary of Best Overall Response Based on Investigator's Assessment During Crossover Portion
Intent-to-Treat Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

	Total (N=xx) n (%)
Overall response (confirmed CR + PR)	xx (xx.x)
95% CI*	(xx.x, xx.x)
Best Overall Response	
Complete response (CR)	xx (xx.x)
Confirmed CR	xx (xx.x)
Partial response (PR)	xx (xx.x)
Confirmed PR	xx (xx.x)
Stable disease	xx (xx.x)
Progressive disease	xx (xx.x)
Not Assessable	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* 95% CI for response rate is the exact 95% confidence interval.

Table 14.2.2.8.2
Summary of Best Overall Response Based on Investigator's Assessment During Crossover Portion
By Disease Type
Intent-to-Treat Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Disease Type = MF

	Total (N=xx) n (%)
Overall response (confirmed CR + PR)	xx (xx.x)
95% CI*	(xx.x, xx.x)
Best Overall Response	
Complete response (CR)	xx (xx.x)
Confirmed CR	xx (xx.x)
Partial response (PR)	xx (xx.x)
Confirmed PR	xx (xx.x)
Stable disease	xx (xx.x)
Progressive disease	xx (xx.x)
Not Assessable	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* 95% CI for response rate is the exact 95% confidence interval.

<<Programming Note: Repeat for the following subgroup: Disease Type (SS).>>

The following tables will have a similar layout as Table 14.2.2.8.1 and 14.2.2.8.2:

Table 14.2.2.8.3
Summary of Best Overall Response Based on Investigator's Assessment During Crossover Portion
Efficacy Evaluable Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.2.2.8.4
Summary of Best Overall Response Based on Investigator's Assessment During Crossover Portion
By Disease Type
Efficacy Evaluable Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.2.2.9
Concordance Between Independent Review and Investigator's Assessment for Best Overall Response During Randomized Treatment Period
Intent-to-Treat Set

	Vorinostat N=xx	KW-0761 N=xx
CR by Independent Review	N'= xx	N'= xx
Agreement of CR by Investigator	xx (xx.x)	xx (xx.x)
PR by Investigator	xx (xx.x)	xx (xx.x)
PR by Independent Review	N'= xx	N'= xx
Agreement of PR by Investigator	xx (xx.x)	xx (xx.x)
SD by Investigator	xx (xx.x)	xx (xx.x)
PD by Investigator	xx (xx.x)	xx (xx.x)
SD by Independent Review	N'= xx	N'= xx
Agreement of SD by Investigator	xx (xx.x)	xx (xx.x)
Unable to Evaluate	xx (xx.x)	xx (xx.x)
PD by Independent Review	N'= xx	N'= xx
Agreement of PD by Investigator	xx (xx.x)	xx (xx.x)
PR by Investigator	xx (xx.x)	xx (xx.x)
SD by Investigator	xx (xx.x)	xx (xx.x)
Unable to Evaluate	xx (xx.x)	xx (xx.x)
Unable to Evaluate by Independent Review	N'= xx	N'= xx
Agreement by Investigator	xx (xx.x)	xx (xx.x)
PR by Investigator	xx (xx.x)	xx (xx.x)
SD by Investigator	xx (xx.x)	xx (xx.x)
PD by Investigator	xx (xx.x)	xx (xx.x)

Percentage is calculated using N' as the denominator, where N' is the number of subjects with the specified best response by Independent Review.
Note: If there is no post-baseline tumor assessment or the response for all post-baseline tumor assessments is not assessable or unable to evaluate, the best overall response is classified as unable to evaluate.

Table 14.2.3.1
Summary of Skindex-29 Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

Scale / Time Point / Statistic	Vorinostat (N=xx) Base	Vorinostat (N=xx) Post	Vorinostat (N=xx) Change	KW-0761 (N=xx) Base	KW-0761 (N=xx) Post	KW-0761 (N=xx) Change
Skindex-29 Score						
Baseline						
n	xx			xx		
Mean	xx.x			xx.x		
Std Dev	xx.xx			xx.xx		
Median	xx.x			xx.x		
Minimum	xx			xx		
Maximum	xx			xx		
End of Cycle 1						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx
End of Cycle 3						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx
Etc.						

<<Programming Note: Repeat for each schedule visit for Symptoms Scale Score, Emotions Scale Score, and Functioning Scale Score.>>

Table 14.2.3.2
Analysis of Change in Skindex-29 Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set

Scale / Time Point / Treatment	N*	--Baseline-- Mean (SD)	--Endpoint-- Mean (SD)	Change from Baseline: LS Mean (SE)	95% CI	Treatment Difference (KW-0761 vs. Vorinostat): LS Mean (SE)	95% CI	P-value	Adjusted P-Value
Skindex-29 Score									
End of Cycle 1						xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx	
Vorinostat	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				
KW-0761	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				
End of Cycle 3						xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx	
Vorinostat	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				
KW-0761	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				
End of Cycle 5						xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx	
Vorinostat	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				
KW-0761	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				
Overall Across 6-Month Assessment						xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx	x.xxxx
Vorinostat	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				
KW-0761	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				
End of Cycle 7						xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx	
Vorinostat	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				
KW-0761	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)				

Etc.

* N is the number of subjects with values at baseline and post-baseline.
Note: LS mean, SE, 95% CI and P-value are from MMRM with treatment, disease type, disease stage, and region as fixed effects and baseline score as a covariate. Adjusted P-value is calculated using Sidak method for the overall difference across time points through 6-month assessment (including End of Cycles 1, 3, and 5 timepoints only). Time points beyond Cycle 11 are not included due to the small number of subjects on study after cycle 11.

<<Programming Note: Repeat for Symptoms Scale Score, Emotions Scale Score, and Functioning Scale Score. Adjusted p-value is only presented for the overall treatment difference through 6-month assessment for the Skindex-29 score including the End of Cycle 1, End of Cycle 3, and End of Cycle 5 time points.>>

The following tables will have similar layout as Table 14.2.3.1 and Table 14.2.3.2:

Table 14.2.3.3
Summary of Skindex-29 Score and Change from Baseline by Visit During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.3.4
Analysis of Change in Skindex-29 Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.3.5
Summary of Skindex-29 Score and Change from Baseline by Visit During Crossover Portion
Intent-to-Treat Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

<<Programming Note: For tables 14.2.3.3 and 14.2.3.5, all scheduled timepoints according to the study procedures will be presented. >>

The following tables will have similar layout as Table 14.2.3.1 and Table 14.2.3.2:

Table 14.2.4.1
Summary of FACT-G Total Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.4.2
Analysis of Change in FACT-G Total Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.4.3
Summary of FACT-G Total Score and Change from Baseline by Visit During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.4.4
Analysis of Change in FACT-G Total Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.4.5
Summary of FACT-G Total Score and Change from Baseline by Visit During Crossover Portion
Intent-to-Treat Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.2.4.6
Summary of FACT-G Physical Well-Being Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.4.7
Summary of FACT-G Social Well-Being Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.4.8
Summary of FACT-G Emotional Well-Being Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.4.9
Summary of FACT-G Functional Well-Being Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

<<Programming Note: For tables 14.2.4.1, 14.2.4.3, and 14.2.4.5-14.2.4.9, all scheduled timepoints according to the study procedures will be presented.>>

The following tables will have similar layout as Table 14.2.3.1:

Table 14.2.5.1
Summary of EQ-5D-3L Index Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.5.2
Analysis of Change in EQ-5D-3L Index Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.5.3
Summary of EQ-5D-3L Index Score and Change from Baseline by Visit During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.5.4
Analysis of Change in EQ-5D-3L Index Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.5.5
Summary of EQ-5D-3L Index Score and Change from Baseline by Visit During Crossover Portion
Intent-to-Treat Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

<<Programming Note: For tables 14.2.5.1, 14.2.5.3, and 14.2.5.5, all scheduled timepoints according to the study procedures will be presented.
>>

Table 14.2.5.6
Summary of EQ-5D-3L by Dimension and by Visit During Randomized Treatment Period – Number (%) of Subjects
Intent-to-Treat Set

Dimension / Time Point	Vorinostat (N=xx)			KW-0761 (N=xx)		
	No Problem	Some Problem	Extreme Problem	No Problem	Some Problem	Extreme Problem
Mobility						
Baseline (n/N', %)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
End of Cycle 1(n/N', %)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
End of Cycle 3 (n/N', %)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
End of Cycle 5 (n/N', %)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
End of Cycle 7 (n/N', %)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
End of Cycle 9 (n/N', %)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
End of Cycle 11 (n/N', %)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Etc.						

Note: Percentage is calculated using N' as the denominator, where N' is the number of subjects with valid measurement at the specified time point.

<<Programming Note: Dimensions also to be included: Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression.>>

The following tables will have similar layout as Table 14.2.5.6:

Table 14.2.5.7
Summary of EQ-5D-3L by Dimension and by Visit During Randomized Treatment Period – Number (%) of Subjects
Efficacy Evaluable Set

Table 14.2.5.8
Summary of EQ-5D-3L by Dimension and by Visit During Crossover Portion – Number (%) of Subjects
Intent-to-Treat Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

The following tables will have similar layout as Table 14.2.3.1 and Table 14.2.3.2:

Table 14.2.6.1
Summary of EQ-5D-3L VAS Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.6.2
Analysis of Change in EQ-5D-3L VAS Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.6.3
Summary of EQ-5D-3L VAS Score and Change from Baseline by Visit During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.6.4
Analysis of Change in EQ-5D-3L VAS Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.6.5
Summary of EQ-5D-3L VAS Score and Change from Baseline by Visit During Crossover Portion
Intent-to-Treat Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

<<Programming Note: For tables 14.2.6.1, 14.2.6.3, and14.2.6.5, all scheduled timepoints according to the study procedures will be presented.>>

The following tables will have similar layout as Table 14.2.3.1 and Table 14.2.3.2:

Table 14.2.7.1
Summary of Pruritus Evaluation Itchy Quality of Life Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.7.2
Analysis of Change in Pruritus Evaluation Itchy Quality of Life Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.7.3
Summary of Pruritus Evaluation Itchy Quality of Life Score and Change from Baseline by Visit During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.7.4
Analysis of Change in Pruritus Evaluation Itchy Quality of Life Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.7.5
Summary of Pruritus Evaluation Itchy Quality of Life Score and Change from Baseline by Visit During Crossover Portion
Intent-to-Treat Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

<<Programming Note:

(1) Only the overall score will be presented for Itchy Quality of Life.

(2) For tables 14.2.7.1, 14.2.7.3, and 14.2.7.5, all scheduled timepoints according to the study procedures will be presented.>>

The following table will have a similar layout as Table 14.2.3.1:

Table 14.2.8.1
Summary of Pruritus Evaluation Likert Scale Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

<<*Programming Note: For Table 14.2.8.1, add a row in each time point to display interquartile range after median.*>>

Table 14.2.8.2
Analysis of Change in Pruritus Evaluation Likert Scale Score from Baseline
During Randomized Treatment Period
Intent-to-Treat Set

Time Point / Treatment	N*	--Baseline-- Median (IQR)	--Endpoint-- Median (IQR)	Change from Baseline: Median (IQR)	95% CI	--Treatment Difference (KW-0761 vs. Vorinostat)-- Median (IQR)	95% CI	P-value
End of Cycle 1						xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Vorinostat	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)			
KW-0761	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)			
End of Cycle 3						xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Vorinostat	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)			
KW-0761	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)			
End of Cycle 5						xx.x (xx.xx)	(xx.x, xx.x)	x.xxxx
Vorinostat	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)			
KW-0761	xxx	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	(xx.x, xx.x)			
Etc.								

* N is the number of subjects with values at baseline and post-baseline.
Note: Treatment difference (KW-0761 - Vorinostat) and its 95% CI are estimated using Hodges-Lehmann estimator and Moses method.
P-values are obtained from Wilcoxon Rank Sum test. Time points beyond Cycle 11 are not included due to the small number of subjects on study after cycle 11.

The following tables will have similar layout as Table 14.2.8.1 and Table 14.2.8.2:

Table 14.2.8.3
Summary of Pruritus Evaluation Likert Scale Score and Change from Baseline by Visit During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.8.4
Analysis of Change in Pruritus Evaluation Likert Scale Score from Baseline
During Randomized Treatment Period
Intent-to-Treat Set

Table 14.2.8.5
Summary of Pruritus Evaluation Likert Scale Score and Change from Baseline by Visit During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.8.6
Analysis of Change in Pruritus Evaluation Likert Scale Score from Baseline
During Randomized Treatment Period
Efficacy Evaluable Set

Table 14.2.8.7
Summary of Pruritus Evaluation Likert Scale Score and Change from Baseline by Visit During Crossover Portion
Intent-to-Treat Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

<<Programming Note: For tables 14.2.8.3, 14.2.8.5, and 14.2.8.7, the scheduled timepoint according to the study procedures will be presented.>>

Table 14.2.9.1
Summary of Overall Survival (OS)
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
Subjects Died (n, %)	xx (xx.x)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Overall Survival (months)		
Kaplan-Meier Estimate of OS		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x
------ Treatment Comparison -----		
KW-0761 vs. Vorinostat		
Hazard Ratio (95% CI)**		xx.x (xx.x, xx.x)
Log rank p-value*		x.xxxx
Rate (%) of Being Alive for at Least***		
6 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
12 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
18 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
24 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Etc.		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.
** Hazard ratio and 95% CI are based on Cox proportional hazards model with treatment, disease type, disease stage, and region as factors. P-values is obtained from a stratified log rank test with disease type, disease stage, and region as the stratification factors.
*** Kaplan-Meier estimate.

Table 14.2.9.2
Overall Survival (OS) Analysis Using RPSFT Model
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
Subjects Died (n, %)	xx (xx.x)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Overall Survival (months)		
Kaplan-Meier Estimate of OS		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x
------ Treatment Comparison -----		
KW-0761 vs. Vorinostat		
Hazard Ratio (95% CI)**		xx.x (xx.x, xx.x)
p-value**		x.xxxx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. RPSFT = rank-preserving structural failure time.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.
** Hazard ratio, 95% CIs and p-value are obtained from RPSFT model.

Table 14.2.9.3
Overall Survival (OS) Analysis Using IPCW Model
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
Subjects Died (n, %)	xx (xx.x)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Overall Survival (months)		
Kaplan-Meier Estimate of OS		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x
------ Treatment Comparison -----		
KW-0761 vs. Vorinostat		
Hazard Ratio (95% CI)**		xx.x (xx.x, xx.x)
p-value**		x.xxxx

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. IPCW = inverse probability of censoring weighting.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.
** Hazard ratio, 95% CIs and p-value are obtained from the IPCW model.

Table 14.2.10
Summary of Time to Treatment Failure (TTF)
Intent-to-Treat Set

	Vorinostat N=xxx	KW-0761 N=xxx
Subjects with Treatment Failure (n, %)	xx (xx.x)	xx (xx.x)
Earliest Contributing Events:		
Discontinuation of Randomized Treatment Due to	xx (xx.x)	xx (xx.x)
PD per CTCL response criteria	xx (xx.x)	xx (xx.x)
Clinical progression	xx (xx.x)	xx (xx.x)
Adverse event	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)
Initiation of Another New Anti-cancer Therapy	xx (xx.x)	xx (xx.x)
Subjects Censored (n, %)	xx (xx.x)	xx (xx.x)
Time to Treatment Failure (months)		
Kaplan-Meier Estimate of TTF		
Q1	xx.x	xx.x
Median (95% CI)*	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Q3	xx.x	xx.x
Mean	xx.xx	xx.xx
Standard Deviation	xx.xxx	xx.xxx
Median	xx.xx	xx.xx
Minimum	xx.x	xx.x
Maximum	xx.x	xx.x
------ Treatment Comparison -----		
KW-0761 vs. Vorinostat		
Hazard Ratio (95% CI)**		xx.x (xx.x, xx.x)
Log rank p-value*		x.xxxx
Rate (%) of Being Alive without Treatment Failure for at Least***		
6 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
12 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
18 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
24 months (95% CI)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Etc.		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* 95% CIs are obtained from SAS proc lifetest using loglog transformation.
** Hazard ratio and 95% CI are based on Cox proportional hazards model with treatment, disease type, disease stage, and region as factors. P-values is obtained from a stratified log rank test with disease type, disease stage, and region as the stratification factors.
*** Kaplan-Meier estimate.

Table 14.3.1.1
Overview of Adverse Events During Randomized Treatment Period
Safety Analysis Set

Adverse Event Category	Vorinostat N=xx n (%)	KW-0761 N=xx n (%)
Adverse Events (AEs)		
Any AEs	xx (xx.x)	xx (xx.x)
Any TEAEs	xx (xx.x)	xx (xx.x)
Drug-related TEAEs	xx (xx.x)	xx (xx.x)
NCI/CTCAE Grade III/IV/V AEs		
Any Grade III/IV/V AEs	xx (xx.x)	xx (xx.x)
Any Grade III/IV/V TEAEs	xx (xx.x)	xx (xx.x)
Drug-related Grade III/IV/V TEAEs	xx (xx.x)	xx (xx.x)
Deaths	xx (xx.x)	xx (xx.x)
Serious Adverse Events (SAEs)		
Any SAEs	xx (xx.x)	xx (xx.x)
Treatment-emergent SAEs	xx (xx.x)	xx (xx.x)
Drug-related Treatment-emergent SAEs	xx (xx.x)	xx (xx.x)
Discontinuation Due to AEs		
Any AEs	xx (xx.x)	xx (xx.x)
Any TEAEs	xx (xx.x)	xx (xx.x)
Drug-related TEAEs	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.

Table 14.3.1.2
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) During Randomized Treatment Period
By System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class* Preferred Term*	Vorinostat N=xx n (%)	KW-0761 N=xx n (%)
Subjects with Any TEAEs	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)
Etc. …		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* MedDRA Version 15.1 was used for coding.

The following table will have a similar layout as Table 14.3.1.2:

Table 14.3.1.3
Number (%) of Subjects with Drug-Related Treatment-Emergent Adverse Events (TEAEs) During Randomized Treatment Period
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.4
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) During Randomized Treatment Period
By System Organ Class, Preferred Term, and Highest CTCAE Grade
Safety Analysis Set

System Organ Class* / Preferred Term* / Highest CTCAE Grade	Vorinostat N=xx n (%)	KW-0761 N=xx n (%)
Subjects with Any TEAEs	xx (xx.x)	xx (xx.x)
Grade I	xx (xx.x)	xx (xx.x)
Grade II	xx (xx.x)	xx (xx.x)
Grade III	xx (xx.x)	xx (xx.x)
Grade IV	xx (xx.x)	xx (xx.x)
Grade V	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)
Grade I	xx (xx.x)	xx (xx.x)
Grade II	xx (xx.x)	xx (xx.x)
Grade III	xx (xx.x)	xx (xx.x)
Grade IV	xx (xx.x)	xx (xx.x)
Grade V	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)
Grade I	xx (xx.x)	xx (xx.x)
Grade II	xx (xx.x)	xx (xx.x)
Grade III	xx (xx.x)	xx (xx.x)
Grade IV	xx (xx.x)	xx (xx.x)
Grade V	xx (xx.x)	xx (xx.x)
Etc.		

Note: Percentage is calculated using the number of subjects in the column heading as the denominator. If a subject experienced more than one adverse event within a preferred term, the subject will be counted once in that preferred term at the highest CTCAE grade. If a subject experienced more than one adverse event within an SOC, the subject will be counted once for that SOC at the highest CTCAE grade.
* MedDRA Version 15.1 was used for coding.

The following tables will have similar layout as Table 14.3.1.2 and Table 14.3.1.4:

Table 14.3.1.5
Number (%) of Subjects with Drug-Related Treatment-Emergent Adverse Events (TEAEs) During Randomized Treatment Period
By System Organ Class, Preferred Term, and Highest CTCAE Grade
Safety Analysis Set

Table 14.3.1.6
Number (%) of Subjects with Grade III/IV/V Treatment-Emergent Adverse Events (TEAEs) During Randomized Treatment Period
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.7
Number (%) of Subjects with Drug-Related Grade III/IV/V Treatment-Emergent Adverse Events (TEAEs) During Randomized Treatment Period
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.8
Number (%) of Subjects with Treatment-Emergent Serious Adverse Events During Randomized Treatment Period
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.9
Number (%) of Subjects with Drug-Related Treatment-Emergent Serious Adverse Events During Randomized Treatment Period
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.10
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) Leading to Discontinuation During Randomized Treatment Period
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.11
Number (%) of Subjects with Drug-Related Treatment-Emergent Adverse Events (TEAEs) Leading to Discontinuation During Randomized Treatment Period
By System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.12
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) During Randomized Treatment Period
By Gender, System Organ Class and Preferred Term
Safety Analysis Set

Table 14.3.1.13
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) During Randomized Treatment Period
By Age Group, System Organ Class and Preferred Term
Safety Analysis Set

<<Programming Note: Table 14.3.1.12 and Table 14.3.1.13 will have similar format as Table 14.3.1.2 but paging by subgroup. For Table 14.3.1.13, the following Age Group will be used: <65 years vs. >=65 years.>>

The following tables will have similar layout as Table 14.3.1.1, Table 14.3.1.2, and Table 14.3.1.4:

Table 14.3.2.1
Overview of Adverse Events During Crossover Portion
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.3.2.2
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) Related to KW-0761 During Crossover Portion
By System Organ Class and Preferred Term
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.3.2.3
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) Related to KW-0761 During Crossover Portion
By System Organ Class, Preferred Term, and Highest CTCAE Grade
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.3.2.4
Number (%) of Subjects with Grade III/IV/V Treatment-Emergent Adverse Events (TEAEs) Related to KW-0761 During Crossover Portion
By System Organ Class and Preferred Term
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.3.2.5
Number (%) of Subjects with Treatment-Emergent Serious Adverse Events Related to KW-0761 During Crossover Portion
By System Organ Class and Preferred Term
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.3.2.6
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) Related to KW-0761 Leading to Discontinuation
During Crossover Portion By System Organ Class and Preferred Term
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

<<Programming Note: For Table 14.3.2.1 to 14.3.2.6, only display the total column.>>

Table 14.3.3.1
Number (%) of Subjects with Treatment-Emergent Adverse Events (TEAEs) Related to KW-0761 for Subjects Exposed to KW-0761
By System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class* Preferred Term*	Initially Randomized to KW-0761 N=xx n (%)	Crossed Over to KW-0761** N=xx n (%)	All Subjects Exposed to KW-0761** N=xx n (%)
Subjects with Any TEAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc. …			

Note: Percentage is calculated using the number of subjects in the column heading as the denominator.
* MedDRA Version 15.1 was used for coding.
** For subjects who are randomized to Vorinostat and crossed over to KW-0761, the TEAEs during the crossover portion are summarized.

Table 14.3.3.2
Exposure-Adjusted Incidence Rate of Infections and Infestations During Randomized Treatment Period
By Preferred Term
Safety Analysis Set

	Number(%) of AE		Incidence Rates Per Patient-months of Exposure[a]	
	Vorinostat	KW-0761	Vorinostat	KW-0761
System Organ Class*	N=xx	N=xx		
Preferred Term*	n (%)	n (%)		
INFECTIONS AND INFESTATIONS	xx (xx.x)	xx (xx.x)	#.##	#.##
Preferred Term 1	xx (xx.x)	xx (xx.x)	#.##	#.##
Preferred Term 2				
Preferred Term 3				
Etc.				

Percentage is calculated using the number of subjects in the column heading as the denominator.
If a subject experienced more than one adverse event within an SOC, the subject will be counted once for that SOC. If a subject experienced more than one adverse event within a preferred term, the subject will be counted once for that preferred term.
* MedDRA Version xx.x was used for coding.
[a] Incidence Rates per Patient-months of Exposure = (Number of patients with AEs/sum of days at risk for AEs) * 30.42 days/month, where days at risk is defined as the last dose date of randomized treatment - first dose date of randomized treatment + 90 for subjects who did not crossover and first dose date of KW-0761 - first dose date of randomized treatment for subjects who crossed over.

Table 14.3.3.3
Exposure-Adjusted Event Rate of Infections and Infestations During Randomized Treatment Period
By Preferred Term
Safety Analysis Set

	Number(%) of AE		Event Rates Per Patient-months of Exposure[a]	
System Organ Class*	Vorinostat N=xx	KW-0761 N=xx	Vorinostat	KW-0761
Preferred Term*	n (%)	n (%)		
INFECTIONS AND INFESTATIONS	xx (xx.x)	xx (xx.x)	#.##	#.##
Preferred Term 1	xx (xx.x)	xx (xx.x)	#.##	#.##
Preferred Term 2				
Preferred Term 3				
Etc.				

Percentage is calculated using the number of subjects in the column heading as the denominator.
If a subject experienced more than one adverse event within an SOC, the subject will be counted once for that SOC. If a subject experienced more than one adverse event within a preferred term, the subject will be counted once for that preferred term.
* MedDRA Version xx.x was used for coding.
[a] Event Rates per Patient-months of Exposure = (Number of AEs/sum of days at risk for AEs) * 30.42 days/month, where days at risk is defined as the last dose date of randomized treatment - first dose date of randomized treatment + 90 for subjects who did not crossover and first dose date of KW-0761 - first dose date of randomized treatment for subjects who crossed over.

The following tables will have similar layout as Table 14.3.3.2 and Table 14.3.3.3:

Table 14.3.3.4
Exposure-Adjusted Incidence Rate of Respiratory, Thoracic and Mediastinal Disorders During Randomized Treatment Period
By Preferred Term
Safety Analysis Set

Table 14.3.3.5
Exposure-Adjusted Event Rate of Respiratory, Thoracic and Mediastinal Disorders During Randomized Treatment Period
By Preferred Term
Safety Analysis Set

Table 14.3.3.6
Exposure-Adjusted Incidence Rate of Renal and Urinary Disorders During Randomized Treatment Period
By Preferred Term
Safety Analysis Set

Table 14.3.3.7
Exposure-Adjusted Event Rate of Renal and Urinary Disorders During Randomized Treatment Period
By Preferred Term
Safety Analysis Set

Table 14.3.3.8
Exposure-Adjusted Incidence Rate of Musculoskeletal and Connective Tissue Disorders During Randomized Treatment Period
By Preferred Term
Safety Analysis Set

Table 14.3.3.9
Exposure-Adjusted Event Rate of Musculoskeletal and Connective Tissue During Randomized Treatment Period
By Preferred Term
Safety Analysis Set

Table 14.3.4.1
Shift Table for Selected Laboratory Parameters During Randomized Treatment Period – Serum Chemistry
Safety Analysis Set

Parameter (Unit) Treatment Arm	N'	Baseline	---- Highest CTCAE Grade During Randomized Treatment Period ---- <=Grade II	>=Grade III	Total
XXX (Unit)					
Vorinostat					
(N=xx)	xx	<=Grade II	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>=Grade III	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)
KW-0761					
(N=xx)	xx	<=Grade II	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>=Grade III	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.					

Note: Percentage is calculated using N' as the denominator where N' is the number of subjects with both baseline and post baseline measurements for the specified parameter.

<<Programming Note: parameters in this table include: AST, ALT, Alkaline Phosphatase, Albumin, Creatinine, Glucose, Total Bilirubin, Phosphorus, and Magnesium. High shifts and low shifts will be summarized for parameters with separate CTC grade criteria for low values and high values (i.e., Glucose and Magnesium).>>

Table 14.3.4.2
Shift Table for Selected Laboratory Parameters During Randomized Treatment Period – Hematology
Safety Analysis Set

Parameter (Unit) Treatment Arm	N′	Baseline	---- Highest CTCAE Grade During Randomized Treatment Period ---- <=Grade II	>=Grade III	Total
XXX (Unit)					
Vorinostat					
(N=xx)	xx	<=Grade II	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>=Grade III	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)
KW-0761					
(N=xx)	xx	<=Grade II	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>=Grade III	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.					

Note: Percentage is calculated using N′ as the denominator where N′ is the number of subjects with both baseline and post baseline measurements for the specified parameter.

<<Programming Note: parameters in this table include: Hemoglobin, WBC, Platelet Count, Lymphocytes, ANC, and CD4. >>

The following tables will have similar layout as Tables 14.3.4.1 and 14.3.4.2:

Table 14.3.4.3
Shift Table for Selected Laboratory Parameters During Crossover Portion – Serum Chemistry
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.3.4.4
Shift Table for Selected Laboratory Parameters During Crossover Portion – Hematology
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

<<Programming Note: For tables 14.3.4.3 and 14.3.4.4, the highest CTCAE Grade during Crossover Period will be presented.>>

Table 14.3.4.5
Number (%) of Subjects with Grade >=III Laboratory Values for Selected Hematology Parameters
Safety Analysis Set

Period Parameter	Vorinostat N=xx n/N' (%)	KW-0761 N=xx n/N' (%)
During Randomized Treatment Period		
White Blood Cell Count	xx/xx (xx.x)	xx/xx (xx.x)
Hemoglobin	xx/xx (xx.x)	xx/xx (xx.x)
Platelet Count	xx/xx (xx.x)	xx/xx (xx.x)
Absolute Neutrophil Count (ANC)	xx/xx (xx.x)	xx/xx (xx.x)
During Crossover Period		
White Blood Cell Count	xx/xx (xx.x)	
Hemoglobin	xx/xx (xx.x)	
Platelet Count	xx/xx (xx.x)	
Absolute Neutrophil Count (ANC)	xx/xx (xx.x)	

Note: Percentage is calculated using N' as the denominator, where N' is the number of subjects with valid post-baseline values for the specified period and parameter.

Table 14.3.5.1
Summary of Vital Signs and Change from Baseline During Randomized Treatment Period
Safety Analysis Set

Parameter / Time Point / Statistic	Vorinostat (N=xx)			KW-0761 (N=xx)		
	Base	Post	Change	Base	Post	Change
Pulse Rate (bpm)						
Baseline						
n	xx			xx		
Mean	xx.x			xx.x		
Std Dev	xx.xx			xx.xx		
Median	xx.x			xx.x		
Minimum	xx			xx		
Maximum	xx			xx		
Maximum Post-baseline Value						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx
Minimum Post-baseline Value						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx
End of Treatment*						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx

* End of Treatment is defined as the measurement obtained at the End of Treatment Visit during the randomized treatment period. If missing, the last post-baseline measurement during randomized treatment period is used.

<<Programming Note: Parameters also to be included in the table: Systolic blood pressure, Diastolic blood pressure, Temperature, Respiratory Rate, and Body Weight.>>

The following tables will have similar layout as Table 14.3.5.1:

Table 14.3.5.2
Summary of Vital Signs and Change from Baseline During Crossover Portion
Safety Analysis Set
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Table 14.3.6.1
Summary of QTcB and QTcF and Change from Baseline During Randomized Treatment Period
Safety Analysis Set

<<Programming Note: For table 14.3.6.1, only include timepoints of baseline and end of treatment.>>

Table 14.3.6.2
Number (%) of Subjects with Abnormal QTcB and QTcF During Randomized Treatment Period
Safety Analysis Set

Parameter Visit Criteria	Vorinostat N=xx n (%)	KW-0761 N=xx n (%)
QTcB (msec)	N'=xx	N'=xx
Baseline		
>450 msec	xx (xx.x)	xx (xx.x)
>480 msec	xx (xx.x)	xx (xx.x)
>500 msec	xx (xx.x)	xx (xx.x)
End of Treatment Visit	N'=xx	N'=xx
>450 msec	xx (xx.x)	xx (xx.x)
>480 msec	xx (xx.x)	xx (xx.x)
>500 msec	xx (xx.x)	xx (xx.x)
Increase >30 msec	xx (xx.x)	xx (xx.x)
Increase >60 msec	xx (xx.x)	xx (xx.x)
Overall for Post-baseline*	N'=xx	N'=xx
>450 msec	xx (xx.x)	xx (xx.x)
>480 msec	xx (xx.x)	xx (xx.x)
>500 msec	xx (xx.x)	xx (xx.x)
Increase >30 msec	xx (xx.x)	xx (xx.x)
Increase >60 msec	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using N' as the denominator, where N' is the number of subjects with valid ECG measurement at the specified visit (time point).
* Any post-baseline measurement including both scheduled and unscheduled measurements.

<<Programming Note: Repeat for QTcF.>>

Table 14.3.6.3
Shift Table for QTcB and QTcF (msec) from Baseline During Randomized Treatment Period
Safety Analysis Set

Parameter / Treatment Arm	N'	Baseline	Most Severe Value During Randomized Treatment Period: <=450	>450 and <=480	>480 and <=500	>500	Total
QTcB (msec)							
Vorinostat (N=xx)	xxx	<=450	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>450 and <=480	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>480 and <=500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KW-0761 (N=xx)	xxx	<=450	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>450 and <=480	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>480 and <=500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
QTcF (msec)							
Vorinostat (N=xx)	xxx	<=450	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>450 and <=480	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>480 and <=500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KW-0761 (N=xx)	xxx	<=450	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>450 and <=480	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>480 and <=500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		>500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentage is calculated using N' as the denominator, where N' is the number of subjects with both baseline and post baseline QTcB or QTcF measurements.

Table 14.3.7
ECOG Performance Status Mean and Mean Change from Baseline by Selected Visits During Randomized Treatment Period
Intent-to-Treat Set

Scale / Time Point / Statistic	Vorinostat (N=xx) Base	Vorinostat (N=xx) Post	Vorinostat (N=xx) Change	KW-0761 (N=xx) Base	KW-0761 (N=xx) Post	KW-0761 (N=xx) Change
ECOG Performance Status						
Baseline						
n	xx			xx		
Mean	xx.x			xx.x		
Std Dev	xx.xx			xx.xx		
Median	xx.x			xx.x		
Minimum	xx			xx		
Maximum	xx			xx		
End of Cycle 1						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx
End of Cycle 3						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Std Dev	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx
Etc.						

<<Programming Note: Present for odd cycles..>>

Table 14.3.8.1
Anti-KW-0761 Antibody Response
Safety Analysis Set (Subjects Exposed to KW-0761)

		Anti-KW-0761 Antibody Status n/N' (%)			Neutralizing n/N' (%)
Treatment Arm	Visit*	Positive	Negative	Inconclusive[a)]	Positive
Initially Randomized to KW-0761 (N=xx)					
	Baseline	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	End of Cycle 1	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	End of Cycle x	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	End of Cycle x	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	.				
	.				
	.				
	EOT	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)	x/xx (xx.x)
	Overall	x/xx (xx.x)			
Crossed Over to KW-0761 (N=xx)					
	.				
	.				
All Subjects Exposed to KW-0761 (N=xx)					
	.				
	.				

* For subjects who cross over, the cycle number corresponds to the treatment cycle of KW-0761.
a) Inconclusive because KW-0761 concentration is higher than drug tolerance limit (16000 ng/mL) or KW-0761 concentration is not determined.
Note: Percentage is calculated using N' as the denominator, where N' is the number of subjects with valid measurements for anti-KW-0761 antibody at the specified visit. Overall is positive if at least one post-baseline assessment (including unscheduled) is positive.

Table 14.3.8.2
Summary of Positive Anti-KW-0761 Antibody Response at Post-Baseline and Infusion Reaction
Safety Analysis Set(Subjects Exposed to KW-0761)

	All Subjects Exposed to KW-0761 N=xx
Number of Infusion Reactions (Events)	xx
Number of Subjects who Experienced Infusion Reactions (n, %)*	xx (xx.x)
Number of Subjects who Experienced Infusion Reaction and who had Overall Assay at Any Time Post-Baseline	N'=xx
Number of Subjects who Experienced Infusion Reaction and who had a Positive Overall Assay at Any Time Post-Baseline (n, %)**	xx (xx.x)
Anti KW-0761 antibody	xx (xx.x)
Neutralizing	xx (xx.x)

Note: Overall assay is positive if at least one of the two assays (Anti KW-0761 antibody or neutralizing) is positive.
* Percentage is calculated using the number of subjects exposed to KW-0761 as the denominator.
** Percentage is calculated using N' as the denominator.

Table 14.3.9

Summary of Pharmacokinetic Concentrations of KW-0761 (ng/mL)

PK Analysis Set

	Cycle 1									
	Day 1						Day 8	Day 15	Day 22	Day 28
	Pre-dose	End of Infusion	6-8 Hrs	24 Hrs	48 Hrs	72-96 Hrs	Pre-dose	Pre-dose	Pre-dose	
N										
Mean										
Std Dev										
Median										
Minimum										
Maximum										

Note: BLQ values (<12.5) are set to 0 for the summary. If a subject had multiple concentrations at a single time point, the average value is used.

Table 14.3.9

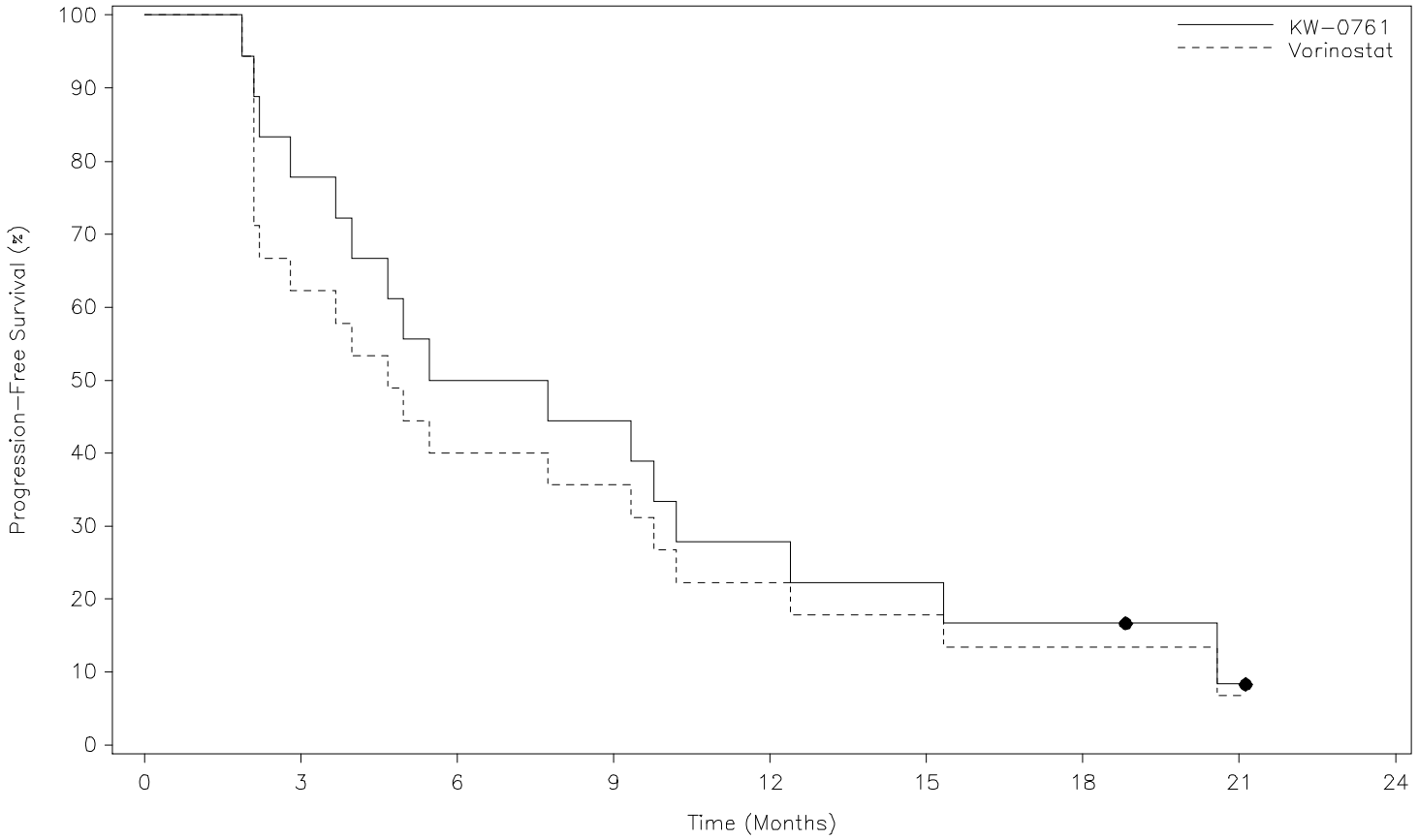
Summary of Pharmacokinetic Concentrations of KW-0761 (ng/mL)

PK Analysis Set

	Cycle 2		Cycle 3		
	Day 1	Day 15	Day 1	Day 15	
Subject	Pre-dose	Pre-dose	Pre-dose	Pre-dose	End of Treatment Visit
N					
Mean					
Std Dev					
Median					
Minimum					
Maximum					

Note: BLQ values (<12.5) are set to 0 for the summary. If a subject had multiple concentrations at a single time point, the average value is used.

Figure 14.2.1
Plot of Kaplan-Meier Curve of Progression-Free Survival by Investigator's Assessment
Intent-to-Treat Set



No. at Risk:

KW:	##	##	##	##	##	##	##	##	##
VOR:	##	##	##	##	##	##	##	##	##

Note: KW = KW–0761; VOR = Vorinostat.

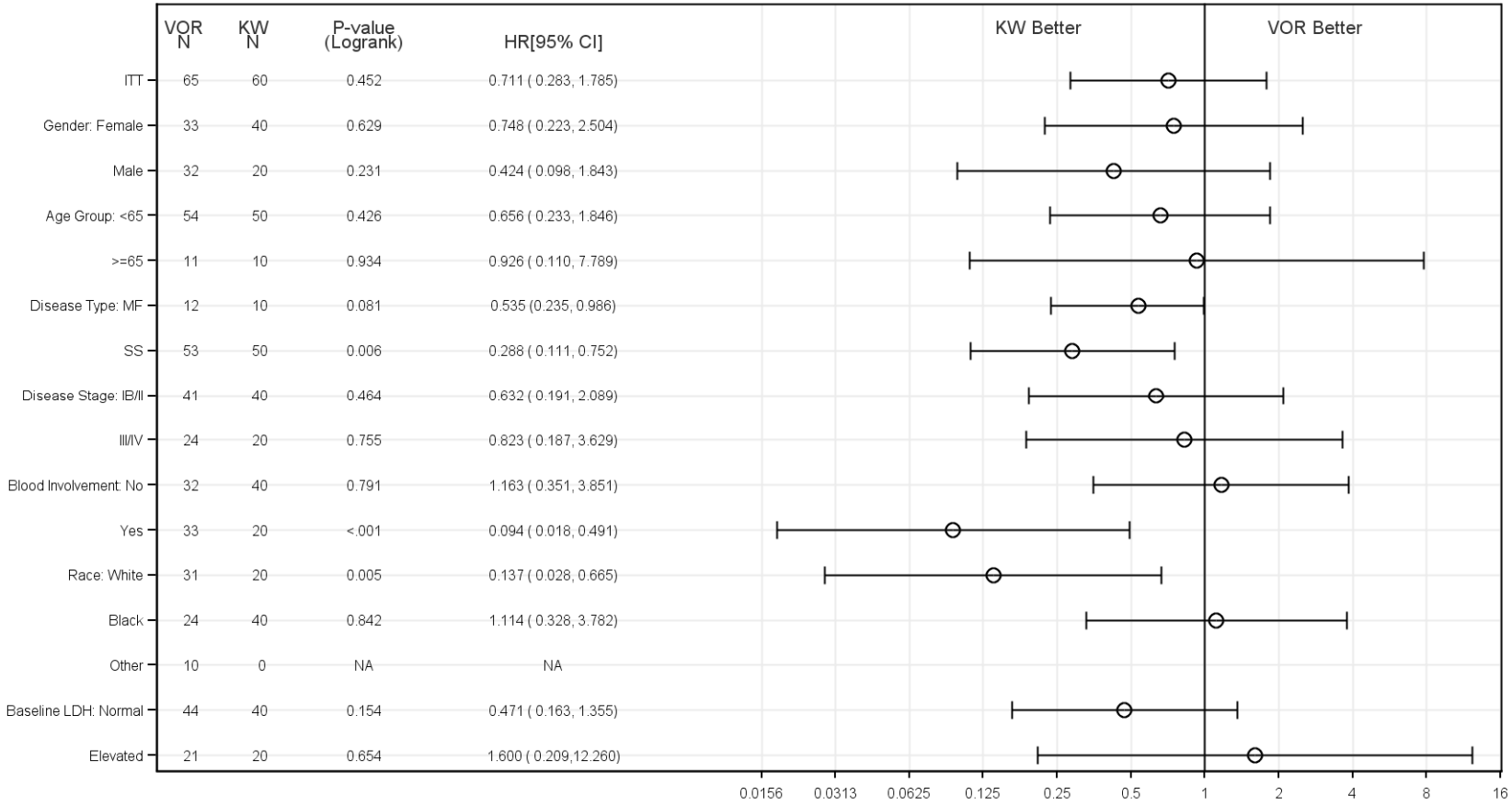
The following figures will have similar layout as Figure 14.2.1:

Table 14.2.2
Plot of Kaplan-Meier Curve of Progression-Free Survival by Investigator's Assessment
Efficacy Evaluable Set

Table 14.2.3
Plot of Kaplan-Meier Curve of Progression-Free Survival by Independent Review
Intent-to-Treat Set

Table 14.2.4
Plot of Kaplan-Meier Curve of Progression-Free Survival by Independent Review
Efficacy Evaluable Set

Table 14.2.5
Forest Plot of Hazard Ratios for Progression-Free Survival Based on Investigator's Assessment by Pre-defined Subgroups
Intent-to-Treat Set



KW = KW-0761; VOR = Vorinostat; HR = Hazard Ratio
Hazard ratio (KW-0761 vs. Vorinostat) and 95% CI are based on Cox proportional hazards model with treatment as a covariate for each subgroup.

The following figure will have a similar layout as Figure 14.2.5:

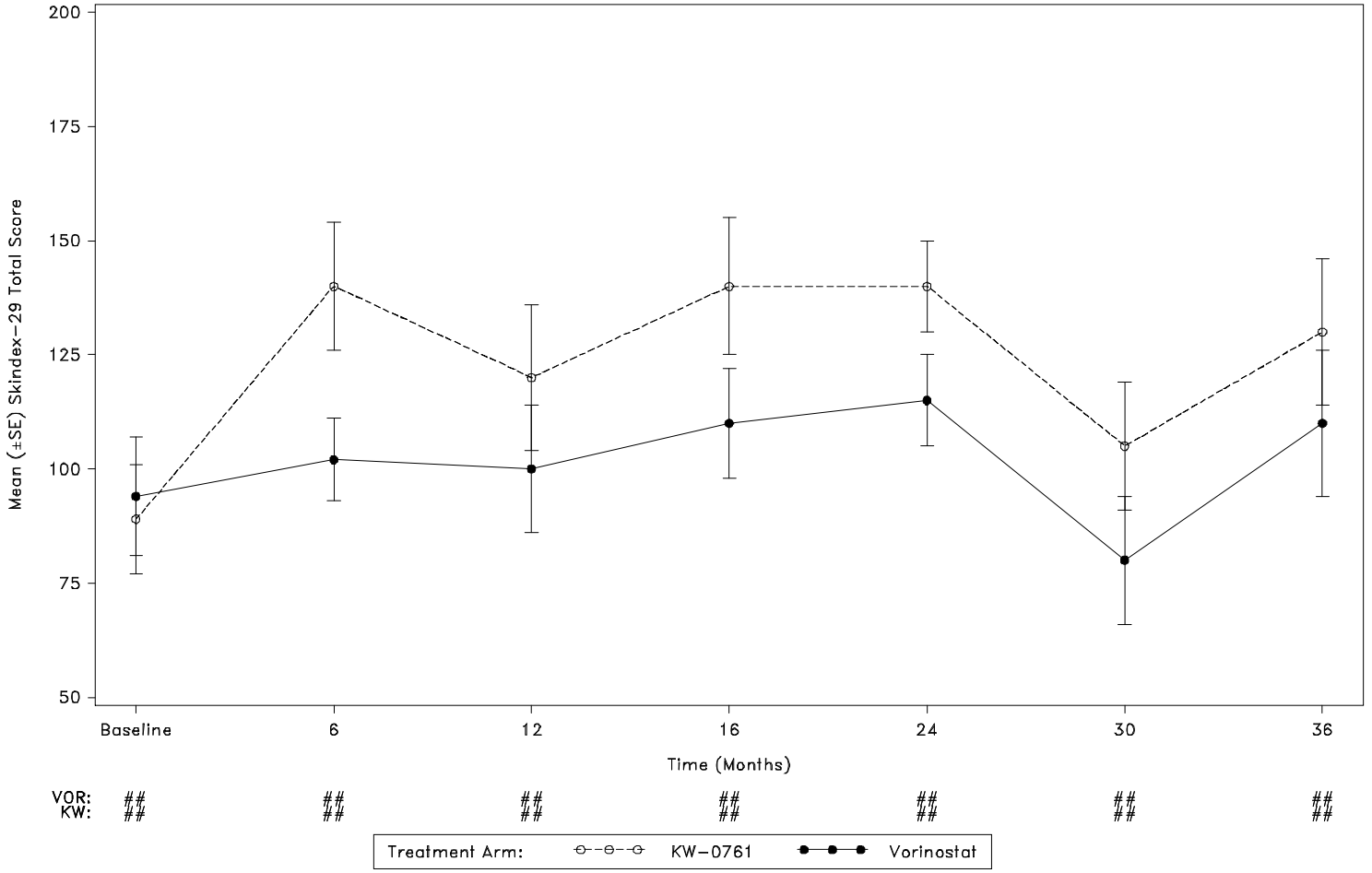
Table 14.2.6
Forest Plot of Hazard Ratios for Progression-Free Survival Based on Investigator's Assessment by Pre-defined Subgroups
Efficacy Evaluable Set

The following figures will have a similar layout as Figure 14.2.1:

Table 14.2.7.1
Plot of Kaplan-Meier Curve of Overall Survival
Intent-to-Treat Set

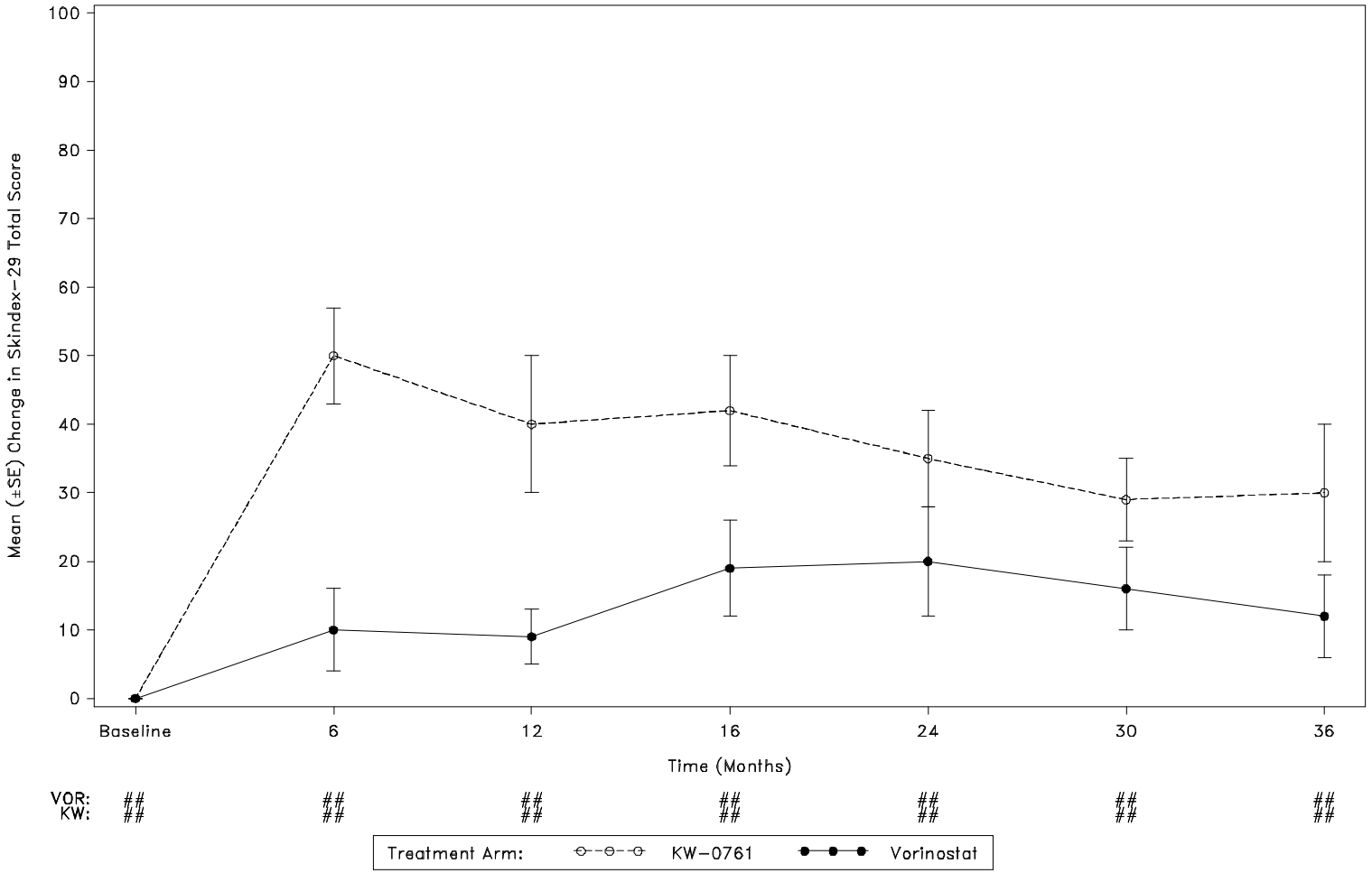
Table 14.2.7.2
Plot of Kaplan-Meier Curve of Time to Treatment Failure
Intent-to-Treat Set

Figure 14.2.8
Mean (±SE) Skindex-29 Score During Randomized Treatment Period
Intent-to-Treat Set



Note: VOR = Vorinostat; KW = KW-0761.
Baseline is defined as the last measurement obtained prior to the first dose of study drug.

Figure 14.2.9
Mean (±SE) Change in Skindex-29 Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set



Note: VOR = Vorinostat; KW = KW-0761.
Baseline is defined as the last measurement obtained prior to the first dose of study drug.

The following figures will have similar layout as Figure 14.2.8 and Figure 14.2.9:

Figure 14.2.10
Mean (±SE) Skindex-29 Score During Randomized Treatment Period
Efficacy Evaluable Set

Figure 14.2.11
Mean (±SE) Change in Skindex-29 Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Figure 14.2.12
Mean (±SE) FACT-G Total Score During Randomized Treatment Period
Intent-to-Treat Set

Figure 14.2.13
Mean (±SE) Change in FACT-G Total Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set

Figure 14.2.14
Mean (±SE) FACT-G Total Score During Randomized Treatment Period
Efficacy Evaluable Set

Figure 14.2.15
Mean (±SE) Change in FACT-G Total Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Figure 14.2.16
Mean (±SE) EQ-5D-3L Index Score During Randomized Treatment Period
Intent-to-Treat Set

Figure 14.2.17
Mean (±SE) Change in EQ-5D-3L Index Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set

Figure 14.2.18
Mean (±SE) EQ-5D-3L Index Score During Randomized Treatment Period
Efficacy Evaluable Set

Figure 14.2.19
Mean (±SE) Change in EQ-5D-3L Index Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Figure 14.2.20
Mean (±SE) Pruritus Evaluation Itchy Quality of Life Score During Randomized Treatment Period
Intent-to-Treat Set

Figure 14.2.21
Mean (±SE) Change in Pruritus Evaluation Itchy Quality of Life Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set

Figure 14.2.22
Mean (±SE) Pruritus Evaluation Itchy Quality of Life Score During Randomized Treatment Period
Efficacy Evaluable Set

Figure 14.2.23
Mean (±SE) Change in Pruritus Evaluation Itchy Quality of Life Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Figure 14.2.24
Mean (±SE) Pruritus Evaluation Likert Scale Score During Randomized Treatment Period
Intent-to-Treat Set

Figure 14.2.25
Mean (±SE) Change in Pruritus Evaluation Likert Scale Score from Baseline During Randomized Treatment Period
Intent-to-Treat Set

Figure 14.2.26
Mean (±SE) Pruritus Evaluation Likert Scale Score During Randomized Treatment Period
Efficacy Evaluable Set

Figure 14.2.27
Mean (±SE) Change in Pruritus Evaluation Likert Scale Score from Baseline During Randomized Treatment Period
Efficacy Evaluable Set

Listing 16.2.1.1
Disposition - End of Treatment

Trt Arm Subject	First Dose Date/Last Dose Date*	Crossed Over to KW-0761?	First/Last Dose Date of KW-0761 after Crossover	Reason for Study Drug Discontinuation	Date of Progression	Date of Death
Vorinostat						
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	Yes	YYYY-MM-DD/ YYYY-MM-DD	Subject withdrawal of consent		
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	No		Progressive disease per CTCL response criteria	YYYY-MM-DD	
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	No		Progressive disease – Clinical: xxxx xxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	Yes	YYYY-MM-DD/ YYYY-MM-DD	Death: xxxxxxx		YYYY-MM-DD
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	No		Withdrawal of consent		
KW-0761						
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD			Other: xxxxxxxxxxxxxxxxxxxxx		
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD			Adverse Event: xxxxxxxxxxxxxxxxxxx		
Etc.						

* First dose date/last dose date of randomized study drug.

Listing 16.2.1.2
Subjects Randomized to Vorinostat and Crossed Over to KW-0761

Subject	Subject Crossed Over to KW-0761 Due to	Date of Approval of Cross-over	By Whom
xxx-xxx	Progression	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxx
xxx-xxx	Intolerance		
xxx-xxx	Progression	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	Progression	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxx
xxx-xxx	Progression	YYYY-MM-DD	xxxxxxxxxxxxxxxxxx
xxx-xxx	Progression	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	Progression	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxx
xxx-xxx	Progression	YYYY-MM-DD	xxxxxxxxxxxxxxxxxx
Etc.			

Listing 16.2.1.3
Disposition - End of Study

Trt Arm Subject	Date of Study Termination	Reason for Study Termination	Date of Death
Vorinostat			
xxx-xxx	YYYY-MM-DD	Withdrawal of consent	
xxx-xxx	YYYY-MM-DD	Lost to Follow-up	
xxx-xxx	YYYY-MM-DD	Death: xxxxxx	YYYY-MM-DD
xxx-xxx	YYYY-MM-DD	Withdrawal of consent	
xxx-xxx	YYYY-MM-DD	Lost to Follow-up	
xxx-xxx	YYYY-MM-DD	Lost to Follow-up	
KW-0761			
xxx-xxx	YYYY-MM-DD	Other: xxxxxxxxxxxxxxxxxxxxx	
xxx-xxx	YYYY-MM-DD	Withdrawal of consent	
Etc.			

Listing 16.2.2.1
Protocol Deviations

Trt Arm Subject	Category	Description	Occurrence Date	Discovery Date	Action Taken
Vorinostat					
xxx-xxx	xxxxxxxxxxxx	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxxxxxxxx	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxxxxxxxx	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxxxxxxxx	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxxxxxxxx	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxxxxxxxx	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxxxxxxxx	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxx
KW-0761					
xxx-xxx	xxxxxxxxxxxx	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxxxxxxxx	xxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxxxxxxxxx

Listing 16.2.2.2
Inclusion/Exclusion Criteria

Trt Arm Subject	All Elig. Criteria Satisfied?	Inc. Criteria* Not Met	Exc. Criteria* Not Met	Waiver Granted?/ Date of Waiver	Waiver Authorized by Whom?	Protocol Version Subject Consented
Vorinostat						
xxx-xxx	Yes					Amendment 1
xxx-xxx	Yes					Amendment 1
xxx-xxx	No	xx, xx		Yes/YYYY-MM-DD	xxxxxxxxxxxxxxxxxx	Amendment 1
xxx-xxx	Yes					Amendment 2
xxx-xxx	Yes					Amendment 2
xxx-xxx	Yes					Amendment 2
xxx-xxx	Yes					Amendment 2
KW-0761						
xxx-xxx	Yes					Amendment 2
xxx-xxx	Yes					Amendment 2

* See the last pages of the listing for a complete list of the inclusion and exclusion criteria.

Listing 16.2.3
Analysis Population

Trt Arm Subject	Intent-to-Treat Set	Safety Analysis Set	Efficacy Evaluable Set	Reasons for Exclusion from Efficacy Evaluable Set
Vorinostat				
xxx-xxx	Yes	Yes	No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	Yes	Yes	Yes	
xxx-xxx	Yes	Yes	Yes	
xxx-xxx	Yes	Yes	No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	Yes	No	No	xxxxxxxxxxxxxx
xxx-xxx	Yes	Yes	Yes	
xxx-xxx	Yes	Yes	No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	Yes	No	No	xxxxxxxxxxxxxx
KW-0761				
xxx-xxx	Yes	Yes	No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	Yes	Yes	Yes	
xxx-xxx	Yes	Yes	Yes	
xxx-xxx	Yes	Yes	Yes	
Subjects Crossed over to KW-0761 (Crossover Portion)				
xxx-xxx	Yes	Yes	Yes	
xxx-xxx	Yes	Yes	Yes	

Listing 16.2.4.1
Demographics

Trt Arm Subject	Date of Informed Consent	Date of Randomization	Age (yrs)*	Gender	Race	Ethnicity	Child-bearing Potential**	BSA (m^2)	BMI (kg/m^2)
Non-Randomized									
xxx-xxx	YYYY-MM-DD		xx	Male	xxxxxxxxx	xxxxxxx		xx.x	xx.x
xxx-xxx	YYYY-MM-DD		xx	Female	Other: xxxxxxxxx	xxxxxxxx	Yes	xx.x	xx.x
Vorinostat									
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Male	xxxxxxxxx	xxxxxxx		xx.x	xx.x
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Female	Other: xxxxxxxxx	xxxxxxxx	No	xx.x	xx.x
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Male	xxxxxxxxx	xxxxxxx		xx.x	xx.x
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Male	xxxxxxxxx	xxxxxxx		xx.x	xx.x
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Female	Other: xxxxxxxxx	xxxxxxxx	Yes	xx.x	xx.x
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Female	Other: xxxxxxxxx	xxxxxxxx	No	xx.x	xx.x
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Male	xxxxxxxxx	xxxxxxx		xx.x	xx.x
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Female	Other: xxxxxxxxx	xxxxxxxx	No	xx.x	xx.x
KW-0761									
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Male	xxxxxxxxx	xxxxxxx		xx.x	xx.x
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Female	Other: xxxxxxxxx	xxxxxxxx	No	xx.x	xx.x
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	xx	Female	Other: xxxxxxxxx	xxxxxxxx	No	xx.x	xx.x

Note: BSA = body surface area at baseline; BMI = body mass index at baseline.
* Age at screening.
** For Female only.

Listing 16.2.4.2
Current CTCL History

Trt Arm Subject	Date of Initial Diagnosis	Histologically Confirmed Diagnosis	Clinical Stage at Diagnosis	Current Clinical Stage	Current T,N,M,B Classification T	 N	 M	 B	Current Sites of Disease	CCR4 Expression Status
Vorinostat										
xxx-xxx	YYYY-MM-DD	MF	IA	IIA	xx	xx	xx	xx	xxxxxxx, xxxxx	Positive
xxx-xxx	YYYY-MM-DD	MF	IB	IIB	xx	xx	xx	xx	xxxxxxx	Positive
xxx-xxx	YYYY-MM-DD	MF	IIA	IIIA	xx	xx	xx	xx	xxxxxxx, xxxx	Negative
xxx-xxx	YYYY-MM-DD	SS	IIB	IIIB	xx	xx	xx	xx	xxxxxxx, xxxxx	Positive
xxx-xxx	YYYY-MM-DD	SS	IIIA	IVA_1	xx	xx	xx	xx	xxxxxxx	Positive
xxx-xxx	YYYY-MM-DD	MF	IIIB	IVA_2	xx	xx	xx	xx	xxxxxxx, xxxx	Negative
xxx-xxx	YYYY-MM-DD	SS	IVA_1	IVB	xx	xx	xx	xx	xxxxxxx, xxxxx	Positive
xxx-xxx	YYYY-MM-DD	MF	IVA_2	IVB	xx	xx	xx	xx	xxxxxxx	Positive
xxx-xxx	YYYY-MM-DD	SS	IVB	IVB	xx	xx	xx	xx	xxxxxxx, xxxx	Negative
					xx	xx	xx	xx		
KW-0761										
xxx-xxx	YYYY-MM-DD	MF	IIA	IVB	xx	xx	xx	xx	xxxxxxx, xxxxx	Positive
xxx-xxx	YYYY-MM-DD	SS	IIB	IVB	xx	xx	xx	xx	Other: xxxxxxx	Positive
xxx-xxx	YYYY-MM-DD	MF	IB	IVB	xx	xx	xx	xx	xxxxxxx, xxxx	Negative

Listing 16.2.4.3
Medical/Surgical History

Trt Arm Subject	Any Medical or Surgical History?	Condition/Diagnosis	Start Date	Ongoing?
Vorinostat				
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	Yes
		xxxxxxxxxxxxxxxxxx	YYYY-MM	No
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	Yes
		xxxxxxxxxxxxxxxxxxx	YYYY-MM	No
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	Yes
		xxxxxxxxxxxxxxxxxx	YYYY-MM	No
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	Yes
		xxxxxxxxxxxxxxxxxx	YYYY-MM	No
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	Yes
		xxxxxxxxxxxxxxxxxx	YYYY-MM	No
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	Yes
		xxxxxxxxxxxxxxxxxx	YYYY-MM	No
KW-0761				
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	Yes
		xxxxxxxxxxxxxxxxxx	YYYY-MM	No
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	Yes
		xxxxxxxxxxxxxxxxxx	YYYY-MM	No
Etc.				

Listing 16.2.4.4
Prior CTCL Therapy

Trt Arm Subject	Treatment Administered	Start Date	Stop Date	Best Response to Therapy
Vorinostat				
xxx-xxx	xxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxx
	xxxxxxxxxxxxxx	YYYY-MM	YYYY-MM-DD	xxxxxxxx
xxx-xxx	xxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxx
	Other: xxxxxxxxxxxxxx	YYYY-MM	YYYY-MM-DD	xxxxxxxx
xxx-xxx	xxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxx
	xxxxxxxxxxxxxx	YYYY-MM	YYYY-MM-DD	xxxxxxxx
xxx-xxx	xxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxx
	xxxxxxxxxxxxxxxxxx	YYYY-MM	YYYY-MM-DD	xxxxxxxx
xxx-xxx	xxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxx
	xxxxxxxxxxxxxx	YYYY-MM	YYYY-MM-DD	xxxxxxxx
KW-0761				
xxx-xxx	xxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxx
	xxxxxxxxxxxxxx	YYYY-MM	YYYY-MM-DD	xxxxxxxx
xxx-xxx	xxxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxx
	Other: xxxxxxxxxxxxxxxxxxx	YYYY-MM	YYYY-MM-DD	xxxxxxxx
Etc.				

Listing 16.2.4.5
Prior Radiotherapy

Trt Arm Subject	Any Prior Radiotherapy?	Method	Site Irradiated	Total Dose	Unit	Start Date	Stop Date
Vorinostat							
xxx-xxx	Yes	External	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxx	YYYY-MM-DD	YYYY-MM-DD
			xxxxxxxxxxxxxx	xxxxxxx	xxxxxx	YYYY-MM-DD	YYYY-MM-DD
xxx-xxx	Yes	Systemic	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxxxx	YYYY-MM-DD	YYYY-MM-DD
			xxxxxxxxxxxxxx	xxxxxxxx	xxxxxxx	YYYY-MM-DD	YYYY-MM-DD
xxx-xxx	Yes	External	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxx	YYYY-MM-DD	YYYY-MM-DD
			xxxxxxxxxxxxxx	xxxxxxx	xxxxxx	YYYY-MM-DD	YYYY-MM-DD
xxx-xxx	No						
xxx-xxx	Yes	External	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxx	YYYY-MM-DD	YYYY-MM-DD
			xxxxxxxxxxxxxx	xxxxxxx	xxxxxx	YYYY-MM-DD	YYYY-MM-DD
KW-0761							
xxx-xxx	Yes	External	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxx	YYYY-MM-DD	YYYY-MM-DD
			xxxxxxxxxxxxxx	xxxxxxx	xxxxxx	YYYY-MM-DD	YYYY-MM-DD
xxx-xxx	Yes	External	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxxxx	YYYY-MM-DD	YYYY-MM-DD
			xxxxxxxxxxxxxx	xxxxxxxx	xxxxxxx	YYYY-MM-DD	YYYY-MM-DD
Etc.							

Listing 16.2.4.6
Prior Medications

Trt Arm Subject	VT: Verbatim Term PT: Preferred Term* ATC:ATC Class*	Start Date/ Stop Date	Indication	Taken to Treat AE?	If Yes, Specify AE
Vorinostat					
xxx-xxx	VT: xxxxxxxxxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxxxxxx ATC:xxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD/ YYYY-MM-DD	xxxxxxxx	Yes	xxxxxxxxxxxxx
	VT: xxxxxxxxxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxxxxxx ATC:xxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD/ Ongoing	xxxxxxxx	No	
xxx-xxx	VT: xxxxxxxxxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxxxxxx ATC:xxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD/ YYYY-MM-DD	xxxxxxxx	Yes	xxxxxxxxxxxxx
xxx-xxx	VT: xxxxxxxxxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxxxxxx ATC:xxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD/ YYYY-MM-DD	xxxxxxxx	Yes	xxxxxxxxxxxxx
	VT: xxxxxxxxxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxxxxxx ATC:xxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD/ Ongoing	xxxxxxxx	No	
KW-0761					
xxx-xxx	VT: xxxxxxxxxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxxxxxx ATC:xxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD/ YYYY-MM-DD	xxxxxxxx	Yes	xxxxxxxxxxxxx
	VT: xxxxxxxxxxxxxxxxxxxxx PT: xxxxxxxxxxxxxxxxxxxxx ATC:xxxxxxxxxxxxxxxxxxxxx	YYYY-MM-DD/ Ongoing	xxxxxxxx	No	
Etc.					

* WHO Drug Dictionary (September 2012) was used for coding.

The following listings will have similar layout as Listing 16.2.4.6:

Listing 16.2.4.7
Concomitant Medication During Randomized Treatment Period

Listing 16.2.4.8
Concomitant Medication During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.4.9
Pruritus Medications During the Study

Trt Arm Subject	Any Medications Taken for Pruritus?	Drug Name	Dose	Start Date	Stop Date
Vorinostat					
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxx	xxxx	YYYY-MM-DD	Ongoing
		xxxxxxxxxxxxxx	xxx	YYYY-MM-DD	YYYY-MM-DD
xxx-xxx	No				
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxx	xxxx	YYYY-MM-DD	Ongoing
		xxxxxxxxxxxxxx	xxx	YYYY-MM-DD	YYYY-MM-DD
		xxxxxxxxxxxxxxxxxx	xxxx	YYYY-MM-DD	Ongoing
		xxxxxxxxxxxxxxxxxx	xxxx	YYYY-MM-DD	Ongoing
KW-0761					
xxx-xxx	Yes	xxxxxxxxxxxxxxxxxx	xxxx	YYYY-MM-DD	Ongoing
		xxxxxxxxxxxxxx	xxx	YYYY-MM-DD	YYYY-MM-DD
		xxxxxxxxxxxxxxxxxx	xxxx	YYYY-MM-DD	Ongoing
		xxxxxxxxxxxxxxxxxx	xxxx	YYYY-MM-DD	Ongoing

Etc.

Listing 16.2.5.1
KW-0761 Administration During Randomized Treatment Period

Trt Arm Subject	Infusion Date/ Start Time/ Stop Time	Planned/ Actual Dose (mg)	% Dose Intensity	Actual Volume (mL)	Reason Total Planned Dose Not Administered	Infusion Interrupted?/ Reason	Time of Interruption/ Restart Time	Symptom of Infusion Reaction*	Any IR**
KW-0761 (1.0 mg/kg)									
xxx-xxx	YYYY-MM-DD/ HH:MM/HH:MM	xx.x/xx.x	xx.x	xx		No			
	YYYY-MM-DD/ HH:MM/HH:MM	xx.x/xx.x	xx.x	xx	xxxxxxxxxxxxxxxxxxxx	No			
	YYYY-MM-DD/ HH:MM/HH:MM	xx.x/xx.x	xx.x	xx		Yes/Infusion Reaction	HH:MM/HH:MM	xxx, xxxxx	
Etc.									

* Symptoms of infusion reaction if interrupted for infusion reaction.
** Any Infusion reaction (IR) that did not interrupt or stop the infusion.

The following listing will have a similar layout as Listing 16.2.5.1:

Listing 16.2.5.2
KW-0761 Administration During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.5.3
Vorinostat Administration

Trt Arm Subject	Dose Administered (mg)	Start Date	End Date	Dose Modified?/ Reason	Compliant with Dosing?/Reason
Vorinostat					
xxx-xxx	xx.x	YYYY-MM-DD	YYYY-MM-DD	Yes/xxxxxxxxx	No/xxxxxxxxxxxxxxxxx
	xx.x	YYYY-MM-DD	YYYY-MM-DD	No	Yes
	xx.x	YYYY-MM-DD	YYYY-MM-DD	No	Yes
xxx-xxx	xx.x	YYYY-MM-DD	YYYY-MM-DD	Yes/xxxxxxxxx	No/xxxxxxxxxxxxxxxxx
	xx.x	YYYY-MM-DD	YYYY-MM-DD	No	Yes
	xx.x	YYYY-MM-DD	YYYY-MM-DD	No	Yes
Etc.					

Listing 16.2.5.4
Blood Sampling and Results for Pharmacokinetic Assessment

Trt Arm Subject	Visit	Analysis Visit	Time Point	Sample Collected?	Sample Date/Time	KW-0761 Concentration (ng/mL)
Initially Randomized KW-0761						
xxx-xxx	xxxxxxxxxx	xxxxxxxxxx	Pre-infusion	Yes	YYYY-MM-DD/HH:MM	xxxxxx
			End of Infusion	No		
	xxxxxxxxxx	xxxxxxxxxx	Pre-infusion	Yes	YYYY-MM-DD/HH:MM	xxxxxx
			End of Infusion	Yes	YYYY-MM-DD/HH:MM	
xxx-xxx	xxxxxxxxxx	xxxxxxxxxx	Pre-infusion	Yes	YYYY-MM-DD/HH:MM	xxxxxx
			End of Infusion	Yes	YYYY-MM-DD/HH:MM	xxxxxx
Cross Over to KW-0761						

Listing 16.2.6.1
mSWAT Assessment During Pre-Treatment and Randomized Treatment Period

Trt Arm / Subject	Visit	mSWAT Completed?	Assessment Date	Area	%BSA for Region	%BSA Patch	%BSA Plaque	%BSA Tumor	Total BSA Involvement (%)
Vorinostat									
xxx-xxx	xxxxxxx	Yes	YYYY-MM-DD	xxxxxx	xx	xx	xx	xx	xx
				xxxxxx	xx	xx	xx	xx	
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxx	xx	xx	xx	xx	xx
				xxxxx	xx	xx	xx	xx	
	xxxxxxxx	No							
xxx-xxx	xxxxxxx	Yes	YYYY-MM-DD	xxxxxx	xx	xx	xx	xx	xx
				xxxxxx	xx	xx	xx	xx	
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxx	xx	xx	xx	xx	xx
				xxxxx	xx	xx	xx	xx	
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxxx	xx	xx	xx	xx	xx
xxx-xxx	xxxxxxx	Yes	YYYY-MM-DD	xxxxxx	xx	xx	xx	xx	xx
				xxxxxx	xx	xx	xx	xx	
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxx	xx	xx	xx	xx	xx
				xxxxx	xx	xx	xx	xx	
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxxx	xx	xx	xx	xx	xx
				xxxxx	xx	xx	xx	xx	
KW-0761 1.0 mg/kg									
xxx-xxx	xxxxxxx	Yes	YYYY-MM-DD	xxxxxx	xx	xx	xx	xx	xx
				xxxxxx	xx	xx	xx	xx	
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxx	xx	xx	xx	xx	xx
				xxxxx	xx	xx	xx	xx	
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxxx	xx	xx	xx	xx	xx
				xxxxx	xx	xx	xx	xx	

Listing 16.2.6.2
mSWAT Analysis During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Assessment Date	--------- mSWAT Analysis* --------- %Patch	%Plaque	%Tumor	Total
Vorinostat						
xxx-xxx	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
xxx-xxx	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
xxx-xxx	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
KW-0761						
xxx-xxx	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx
	xxxxxxx	YYYY-MM-DD	xx	xx	xx	xx

* mSWAT Analysis: %BSA patch x 1, %BSA plaque x 2, %BSA tumor x 4.
Note: CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NA = not assessable.

The following listings will have similar layout as Listing 16.2.6.1 and Listing 16.2.6.2:

Listing 16.2.6.3
mSWAT Assessment During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.4
mSWAT Analysis During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.5
Flow Cytometric Analysis During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Blood Involvement?	Visit	Sample Date/Time	Parameter	Unit	Result
Vorinostat						
xxx-xxx	Yes	xxxxxxxx	YYYY-MM-DD/HH:MM	xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
		xxxxxxxx	YYYY-MM-DD/HH:MM	xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
xxx-xxx	Yes	xxxxxxxx	YYYY-MM-DD/HH:MM	xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
KW-0761						
xxx-xxx	Yes	xxxxxxxx	YYYY-MM-DD/HH:MM	xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x
		xxxxxxxx	YYYY-MM-DD/HH:MM	xxxxxxxx	xxx	xx.x
				xxxxxxxx	xxx	xx.x

Note: CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NA = not assessable.

The following listing will have a similar layout as Listing 16.2.6.5:

Listing 16.2.6.6
Flow Cytometric Analysis During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.7
Bone Marrow Aspirate/Biopsy Assessment During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Collection Method	Collection Date	Evidence of Lymphoma?
Vorinostat				
xxx-xxx	xxxxxxxxxxxxx	Aspirate	YYYY-MM-DD	Yes
	xxxxxxxxxxxxx		Not Done	
	xxxxxxxxxxxxx	Aspirate	YYYY-MM-DD	Yes
xxx-xxx	xxxxxxxxxxxxx	Aspirate	YYYY-MM-DD	Yes
	xxxxxxxxxxxxx	Aspirate	YYYY-MM-DD	Yes
	xxxxxxxxxxxxx	Aspirate	YYYY-MM-DD	No
xxx-xxx	xxxxxxxxxxxxx	Aspirate	YYYY-MM-DD	Yes
	xxxxxxxxxxxxx	Aspirate	YYYY-MM-DD	Yes
	xxxxxxxxxxxxx	Aspirate	YYYY-MM-DD	No
KW-0761				
xxx-xxx	xxxxxxxxxxxxx	Biopsy	YYYY-MM-DD	Yes
	xxxxxxxxxxxxx	Biopsy	YYYY-MM-DD	Yes
	xxxxxxxxxxxxx	Biopsy	YYYY-MM-DD	No

The following listing will have a similar layout as Listing 16.2.6.7:

Listing 16.2.6.8
Bone Marrow Aspirate/Biopsy Assessment During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.9
Lymph Node Assessment During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Date of Assessment	Enlarged Lymph Nodes?	Lesion No.	Location	Measurement (mm)	Sum of the Product of Diameters (mm)	
Vorinostat								
xxx-xxx	xxxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx	xxx/xxx	xxx	
				xx	xxxxx	xxx/xxx		
	xxxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx	xxx/xxx	xxx	
				xx	xxxxx	xxx/xxx		
	xxxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx	xxx/xxx	xxx	
xxx-xxx	xxxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx	xxx/xxx	xxx	
				xx	xxxxx	xxx/xxx		
	xxxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx	xxx/xxx	xxx	
KW-0761								
xxx-xxx	xxxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx	xxx/xxx	xxx	
				xx	xxxxx	xxx/xxx		
					Other:	xxx/xxx	xxx	xx
	xxxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx			
				xx	xxxxx	xxx/xxx		
	xxxxxxxxx	YYYY-MM-DD	No					

Note: CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NA = not assessable.

The following listing will have a similar layout as Listing 16.2.6.9:

Listing 16.2.6.10
Lymph Node Assessment During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.11
Visceral Mass Assessment During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Method	Date of Assessment	Abnormal Lesions?	Lesion No.	Location	Measure-ment (mm)	Sum of Diam. (mm)*	Non-Measur-able Disease	Description
Vorinostat										
xxx-xxx	xxxxxxx	xxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxxxxx	xxx/xxx	xxx	Yes	xxxxxxxxxxx
					xx	xxxxxxxx	xxx/xxx			
	xxxxxxx	xxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxxxxx	xxx/xxx	xxx	No	
					xx	xxxxx	xxx/xxx			
	xxxxxxx	xxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx				
KW-0761										
xxx-xxx	xxxxxxx	xxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx	xxx/xxx	xxx	No	
					xx	xxxxx	xxx/xxx			
	xxxxxxx	xxxxxxxx	YYYY-MM-DD	Yes	xx	xxxxx	xxx/xxx	xxx	No	
					xx	xxxxx	xxx/xxx			
		Other:		Yes		Other:	xxx/xxx	xxx	No	Other: xxxx
	xxxxxxx	xxxxxxxx	YYYY-MM-DD		xx	xxxxx				

* Sum of the Product of Diameters.
Note: CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NA = not assessable.

The following listing will have a similar layout as Listing 16.2.6.11:

Listing 16.2.6.12
Visceral Mass Assessment During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.13
CTCL Response During Randomized Treatment Period - By Investigator's Assessment

Trt Arm Subject	Visit	Compartment	Date of Assessment	Response
Vorinostat				
xxx-xxx	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
	xxxx	Overall	YYYY-MM-DD	xx
xxx-xxx	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
xxx-xxx	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
KW-0761				
xxx-xxx	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx
	xxxx	xxxxxxxxxx	YYYY-MM-DD	xx

Note: CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NA = not assessable.

The following listing will have similar layout as Listing 16.2.6.13:

Listing 16.2.6.14
CTCL Response During Crossover Portion - By Investigator's Assessment
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.15.1
CTCL Response During Randomized Treatment Period - By Independent Review

Trt Arm / Subject	Date of Exam	Response* Skin	Blood	Lymph Nodes	Visceral	Overall
Vorinostat						
xxx-xxx	2013-12-03	-	SD	-	-	-
	2013-12-17	CR	SD	PD	SD	NA
	2013-12-27	-	SD	-	-	-
	BEST	CR	SD	PD	SD	NA
xxx-xxx	2013-06-19	-	SD	-	-	-
	2013-07-01	-	-	PD	NA	NA
KW-0761						
xxx-xxx	2013-10-17	NA	-	NA	NA	NA
	2013-10-21	NA	NA	-	-	-
	BEST	NA	NA	NA	NA	NA

* CR = complete response; CRu = uncertified complete response; PR = partial response; SD = stable disease; PD = relapsed disease or progressive disease; NA = not assessable.

Listing 16.2.6.15.2

Lymph Node Assessment During Pre-Treatment and Randomized Treatment Period - By Independent Review

Trt Arm Subject	Timepoint	Date of Exam	Sum of Products of Diameters (mm^2)	% Change from Baseline	% Change from Nadir	New Lymph Lesion
Vorinostat						
xxx-xxx	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
KW-0761						
xxx-xxx	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No

Note: CR = complete response; CRu = uncertified complete response, PR = partial response; SD = stable disease; PD = relapsed disease or progressive disease; NA = not assessable.

Listing 16.2.6.15.3

Visceral Assessment During Pre-Treatment and Randomized Treatment Period - By Independent Review

Trt Arm Subject	Timepoint	Date of Exam	Sum of Products of Diameters (mm^2)	% Change from Baseline	% Change from Nadir	New Lesion
Vorinostat						
xxx-xxx	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
KW-0761						
xxx-xxx	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No
	xxxxxxxxxx	YYYY-MM-DD	xxx	xx.x	xx.x	No

Note: CR = complete response; CRu = uncertified complete response, PR = partial response; SD = stable disease; PD = relapsed disease or progressive disease; NA = not assessable.

Listing 16.2.6.16

Progression-Free Survival (PFS) – By Investigator's Assessment

Trt Arm Subject	Disease Type	CCR4 Status	Disease Stage	Age/ Gender/ Race*	Blood Involve-ment	Date of Randomi-zation	Progressive Disease?/ Date of Progression	Death?/Date of Death	Date of Last Tumor Assessment	PFS (Days)
Vorinostat										
xxx-xxx	MF	Positive	IB	xx/M/W	Yes	YYYY-MM-DD	Yes/YYYY-MM-DD	Yes/YYYY-MM-DD	YYYY-MM-DD	xxx
xxx-xxx	SS	Negative	IIA	xx/F/B	No	YYYY-MM-DD	No	No	YYYY-MM-DD**	xxx (C)
xxx-xxx	MF	Positive	IB	xx/F/W	No	YYYY-MM-DD	Yes/YYYY-MM-DD	No	YYYY-MM-DD	xxx
xxx-xxx	SS	Negative	IIA	xx/F/B	Yes	YYYY-MM-DD	No	Yes/YYYY-MM-DD	YYYY-MM-DD	xxx
KW-0761										
xxx-xxx	MF	Positive	IB	xx/M/W	Yes	YYYY-MM-DD	Yes/YYYY-MM-DD	Yes/YYYY-MM-DD	YYYY-MM-DD	xxx
xxx-xxx	SS	Negative	IIA	xx/F/B	No	YYYY-MM-DD	No	No	YYYY-MM-DD**	xxx (C)
xxx-xxx	MF	Positive	IB	xx/F/W	No	YYYY-MM-DD	Yes/YYYY-MM-DD	No	YYYY-MM-DD	xxx
xxx-xxx	SS	Negative	IIA	xx/F/B	Yes	YYYY-MM-DD	No	Yes/YYYY-MM-DD	YYYY-MM-DD	xxx

Note: (C) = censored observation.
* Gender: M = male; F = female. Race: W = White; A = Asian; B = Black or African American; AI = American Indian or Alaska Native; NH = Native Hawaiian or Other Pacific Islander; O = Other; NA = Not applicable.
** If subjects withdraw prior to first tumor assessment, the last documented visit date is provided.

The following listing will have a similar layout as Listing 16.2.6.16:

Listing 16.2.6.17
Progression-Free Survival (PFS) - By Independent Review

Listing 16.2.6.18
Best Response During Randomized Treatment Period – By Investigator's Assessment

Trt Arm Subject	Disease Type	CCR4 Status	Disease Stage	Age/ Gender/ Race*	Blood Involvement	Compartment	Best Response	Date of First Response (Study Day)	Duration of Response** (Days)
Vorinostat									
xxx-xxx	MF	Positive	IB	xx/M/W	Yes	Overall	PD	YYYY-MM-DD (xx)	
						Skin	PD	YYYY-MM-DD (xx)	
						Lymph Nodes	SD	YYYY-MM-DD (xx)	
						Blood	PD	YYYY-MM-DD (xx)	
xxx-xxx	SS	Negative	IIA	xx/F/B	No	Overall	SD	YYYY-MM-DD (xx)	
						Skin	SD	YYYY-MM-DD (xx)	
						Lymph Nodes	SD	YYYY-MM-DD (xx)	
KW-0761									
xxx-xxx	MF	Positive	IB	xx/M/W	Yes	Overall	CR*	YYYY-MM-DD (xx)	xxx(C)
						Skin	CR	YYYY-MM-DD (xx)	
						Lymph Nodes	CR	YYYY-MM-DD (xx)	
						Blood	CR	YYYY-MM-DD (xx)	
xxx-xxx	SS	Negative	IIA	xx/F/B	No	Overall	SD	YYYY-MM-DD (xx)	
						Skin	SD	YYYY-MM-DD (xx)	
						Lymph Nodes	SD	YYYY-MM-DD (xx)	

Note: CR = complete response, PR = partial response, SD = stable disease, PD = progressive disease, NE = not evaluable; * = confirmed response; (C) = censored observation.
Study day is calculated relative to the date of randomization.
* Gender: M = male; F = female. Race: W = White; A = Asian; B = Black or African American; AI = American Indian or Alaska Native; NH = Native Hawaiian or Other Pacific Islander; O = Other; NA = Not applicable.
** Only calculated for subjects who achieved confirmed CR or PR during randomized treatment period.

The following listings will have similar layout as Listing 16.2.6.18:

Listing 16.2.6.19
Best Response During Randomized Treatment Period – By Independent Review

Listing 16.2.6.20
Best Response During Crossover Portion – By Investigator's Assessment
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.21
Skindex-29 Assessment During During Pre-Treatment and Randomized Treatment Period

Trt Arm / Subject Visit	Assessment Date	Question Number* 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Vorinostat																															
xxx-xxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxx-xxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx																															
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**
KW-0761																															
xxx-xxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Note: 1 = Never, 2 = Rarely, 3 = Sometimes, 4 = Often, 5 = All the Time.
* See the first pages of the listing for a complete list of the questions for Skindex-29.

Listing 16.2.6.22
Skindex-29 Score During During Pre-Treatment and Randomized Treatment Period

Trt Arm / Subject	Visit	Assessment Date	Score			
			Overall	Symptoms	Emotions	Functioning
Vorinostat						
xxx-xxx	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
xxx-xxx	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
xxx-xxx	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
KW-0761						
xxx-xxx	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x
	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x

Note: Raw responses were transformed to a linear scale of 0 (no effect) to 100 (effect experienced all the time). Each subscale score is the mean of a subject's responses to the items in the specified subscale. Overall score is the average of the 3 subscale scores.

<<Programming Note: Symptoms scale includes questions 1, 7, 10, 16, 19, 24, 27; Functioning scale includes questions 2, 4, 5, 8, 11, 14, 17, 20, 22, 25, 29, 30; Emotions scale includes questions 3, 6, 9, 12, 13, 15, 21, 23, 26, 28.>>

The following listing will have similar layout as Listing 16.2.6.21 and Listing 16.2.6.22:

Listing 16.2.6.23
Skindex-29 Assessment During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.24
Skindex-29 Score During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

<<Programming Note: Time Point will not be presented for listing 16.2.23 and Listing 16.2.6.24.>>

Listing 16.2.6.25
FACT-G Assessment During During Pre-Treatment and Randomized Treatment Period

Trt Arm / Subject Visit	Assessment Date	Question Number* 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
Vorinostat																												
xxx-xxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxx-xxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx																												
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**
KW-0761																												
xxx-xxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Note: 1 = Not at all, 2 = A little bit, 3 = Some-what, 4 = Quite a bit, 5 = Very much.
* See the first pages of the listing for a complete list of the questions for FACT-G.

Listing 16.2.6.26
FACT-G Subscale and Total Scores During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Assessment Date	PWB	SWB	EWB	FWB	Total
Vorinostat							
xxx-xxx	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
xxx-xxx	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
xxx-xxx	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
KW-0761							
xxx-xxx	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx

Note: PWB = physical well-being, SWB = social/family well-being, EWB = emotional well-being, FWB = functional well-being.
Score Ranges: PWB, SWB and FWB: 0 to 28; EWB: 0 to 24; Total Score: 0 to 108.

The following listings will have similar layout as Listing 16.2.6.25 and Listing 16.2.6.26:

Listing 16.2.6.27
FACT-G Assessment During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.28
FACT-G Subscale and Total Scores During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.29
EQ-5D-3L Assessment and Score During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Assessment Date	Mobility	Self-Care	Usual Activities	Pain/ Discomfort	Anxiety/ Depression	Index Score	VAS Score
Vorinostat									
xxx-xxx	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
xxx-xxx	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
xxx-xxx	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	
KW-0761									
xxx-xxx	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx
	xxxxx	YYYY-MM-DD	xxx	xxx	xxx	xxx	xxx	x.xx	xxx

Note: 1 = no problems, 2 = some problems, 3 = extreme problems. VAS = visual analog scale. See the first pages of the listing for a complete list of the questions for EQ-5D-3L.

The following listing will have a similar layout as Listing 16.2.6.29:

Listing 16.2.6.30
EQ-5D-3L Assessment and Score During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.31
Pruritus Evaluation - Itchy QoL Assessment During During Pre-Treatment and Randomized Treatment Period

Trt Arm / Subject Visit	Assessment Date	Question Number* 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Vorinostat																							
xxx-xxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxx-xxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx																							
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**
KW-0761																							
xxx-xxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxxxx	YYYY-MM-DD	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Note: 1 = Never, 2 = Rarely, 3 = Sometimes, 4 = Often, 5 = All the time.
* See the first pages of the listing for a complete list of the questions for Itchy QoL.

Listing 16.2.6.32
Pruritus Evaluation Score During During Pre-Treatment and Randomized Treatment Period

Trt Arm / Subject	Does Subject have Pruritus?	Visit	Assessment Date	Itchy QoL Score: Total	Itchy QoL Score: Symptom	Itchy QoL Score: Function	Itchy QoL Score: Emotion	Likert Scale of Pruritus	Any Medication Taken?
Vorinostat									
xxx-xxx	Yes	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	Yes
		xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	No
		xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	Yes
		xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	No
xxx-xxx	Yes	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	No
		xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	No
xxx-xxx	Yes	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	Yes
		xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	Yes
KW-0761									
xxx-xxx	Yes	xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	Yes
		xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	No
		xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	Yes
		xxxxx	YYYY-MM-DD	xx.x	xx.x	xx.x	xx.x	xxx	No

Note: For Itchy QoL, item responses for frequency were scored on a 1 (never) to 5 (all of the time) scale. Each subscale score is the mean of a subject's responses to the items in the specified subscale. Total score is the average of the 3 subscale scores.

<<Programming Note: For Itchy QoL, Symptoms scale includes questions 1 to 6; Functioning scale includes questions 7 to 13; Emotions scale includes questions 14 to 22.>>

The following listings will have similar layout as Listing 16.2.6.31 and Listing 16.2.6.32:

Listing 16.2.6.33
Pruritus Evaluation - Itchy QoL Assessment During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.34
Pruritus Evaluation Score During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.35
Skin Biopsy During Randomized During Pre-Treatment and Treatment Period

Trt Arm Subject	Visit	Biopsy Performed?	Collection Date	Result	Reason for Skin Biopsy
Vorinostat					
xxx-xxx	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxx	xxxxxxxxxxxxxxxxxxxxxxx
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxx	xxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxx	xxxxxxxxxxxxxxxxxxxxxxx
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxx	xxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxx	xxxxxxxxxxxxxxxxxxxxxxx
	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxx	xxxxxxxxxxxxxxxxxxxxxxx
KW-0761					
xxx-xxx	xxxxxxxx	Yes	YYYY-MM-DD	xxxxxxx	Other: xxxxxxxxxxxxxxxxxxxxxxx
	xxxxxxxx	Yes		Other:	
			YYYY-MM-DD	xxxxxxx	Skin Rash: xxxxxxxxxxxxxxxxxxxxxxx

The following listing will have a similar layout as Listing 16.2.6.35:

Listing 16.2.6.36
Skin Biopsy During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.6.37
Survival Status

Trt Arm Subject	Date of Contact	Method of Contact	New Anti-Cancer Therapy?	Date of Therapy	Disease Progression?/ Date	Method of Confir-mation	Subject Alive?/Date of Death	Primary Cause of Death	Autopsy Conducted?/ Sig. Findings
Vorinostat									
xxx-xxx	xxxxxxxx	xxxxxxxx	Yes/Specify	YYYY-MM-DD	Yes/YYYY-MM-DD	xxxxxx	Yes		
	xxxxxxxx	xxxxxxxxx	No		No		No/YYYY-MM-DD	xxxxxxxx	No
xxx-xxx	xxxxxxxx	xxxxxxxx	No		No		Yes		
	xxxxxxxx	xxxxxxxxx	No		Yes/YYYY-MM-DD	xxxxx	Yes		
xxx-xxx	xxxxxxxx	xxxxxxxxx	No		No		Yes		
	xxxxxxxx	xxxxxxxx	No		No		No/YYYY-MM-DD	xxxxxxxx	
KW-0761									
xxx-xxx	xxxxxxxx	xxxxxxxxx	Yes/Specify	YYYY-MM-DD	Yes/YYYY-MM-DD	xxxxxx	Yes		
	xxxxxxxx	xxxxxxxx	No		No		No/YYYY-MM-DD	Other: xxxxxxxx	Yes/xxxxxxxx

Listing 16.2.7.1
Adverse Events During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	VT: Verbatim Term PT: MedDRA Preferred Term SOC:System Organ Class	Start Date/Day Stop Date/Day Duration (days)	CTCAE Grade	TEAE	Serious	Relationship	Action Taken/ Outcome	Trt. for AE?
Vorinostat								
xxx-xxx	VT: xxxxxxxxxxxxxxxx PT: xxxxxx SOC:xxxxxxxxxxx	YYYY-MM-DD/xx YYYY-MM-DD/xx xx	x	Yes	No	Not related	xxxxxxxxxx/ xxxxxxxxxx	Yes
xxx-xxx	VT: xxxxxxxxxxxxxxxx PT: xxxxxx SOC:xxxxxxxxxxx	YYYY-MM-DD/xx YYYY-MM-DD/xx xx	x	Yes	Yes	Probably	xxxxxxxxxxxx/ xxxxxxxxxx	No
	VT: xxxxxxxxxxxxxxxx PT: xxxxxx SOC:xxxxxxxxxxx	YYYY-MM-DD/xx YYYY-MM-DD/xx xx	x	Yes	Yes	Probably	xxxxxxxxxxxx/ xxxxxxxxxx	No
xxx-xxx	VT: xxxxxxxxxxxxxxxx PT: xxxxxx SOC:xxxxxxxxxxx	YYYY-MM-DD/xx YYYY-MM-DD/xx xx	x	Yes	No	Not related	xxxxxxxxxx/ xxxxxxxxxx	No
xxx-xxx	VT: xxxxxxxxxxxxxxxx PT: xxxxxx SOC:xxxxxxxxxxx	YYYY-MM-DD/xx YYYY-MM-DD/xx xx	x	Yes	No	Unlikely	xxxxxxxxxxxx/ xxxxxxxxxx	Yes
KW-0761								
xxx-xxx	VT: xxxxxxxxxxxxxxxx PT: xxxxxx SOC:xxxxxxxxxxx	YYYY-MM-DD/xx Ongoing	x	Yes	No	Not related	xxxxxxxxxx/ xxxxxxxxxx	No
xxx-xxx	VT: xxxxxxxxxxxxxxxx PT: xxxxxx SOC:xxxxxxxxxxx	YYYY-MM-DD/xx YYYY-MM-DD/xx xx	x	Yes	No	Unlikely	xxxxxxxxxxxx/ xxxxxxxxxx	Yes

Note: MedDRA Version 15.1 was used for coding. Study day is calculated as start date or stop date of adverse event – date of first dose of study medication + 1. Duration is calculated as stop date of adverse event – start date of adverse event + 1.

The following listings will have similar layout as Listing 16.2.7.1:

Listing 16.2.7.2
Listing of Serious Adverse Events (SAEs) During During Pre-Treatment and Randomized Treatment Period

Listing 16.2.7.3
Listing of Grade III/IV/V Adverse Events During During Pre-Treatment and Randomized Treatment Period

Listing 16.2.7.4
Listing of Adverse Events Leading to Discontinuation of Study Medication During Randomized Treatment Period

Listing 16.2.7.5
Listing of Adverse Events Leading to Death During Randomized Treatment Period

Listing 16.2.7.6
Adverse Events During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.7.7
Listing of Serious Adverse Events (SAEs) During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.7.8
Listing of Grade III/IV/V Adverse Events During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.7.9
Listing of Adverse Events Leading to Discontinuation of Study Medication During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.7.10
Listing of Adverse Events Leading to Death During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

<<Programming Note: For adverse events during the crossover portion, Relationship and Action Taken should be displayed for each study medication.>>

Listing 16.2.8.1
Laboratory Assessment During During Pre-Treatment and Randomized Treatment Period – Chemistry

Trt Arm / Subject	Lab Test	Unit	Normal Range Low-High	Visit	Sample Date/Time	Lab Value	Flag*	CTCAE Grade	CS?
Vorinostat									
xxx-xxx	xxxxxxxxxxxxxxx	xxx	xx.x – xx.x	xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
				xxxxxxx	YYYY-MM-DD/HH:MM	xx.x	H	2	No
				xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
	xxxxxxxxxxxxxx	xxx	xx.x – xx.x	xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
				xxxxxxx	YYYY-MM-DD/HH:MM	xx.x	H	3	Yes
				xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
	xxxxxxxxxxxxxx	xxx	xx.x – xx.x	xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
				xxxxxxx	YYYY-MM-DD/HH:MM	xx.x	L	1	No
				xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
	xxxxxxxxxxxxxxxx	xxx	xx.x – xx.x	xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
				xxxxxxx	YYYY-MM-DD/HH:MM	xx.x	H	1	No
				xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
xxx-xxx	xxxxxxxxxxxxxx	xxx	xx.x – xx.x	xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
				xxxxxxx	YYYY-MM-DD/HH:MM	xx.x	H	0	No
				xxxxxxxx	Not Done				
	xxxxxxxxxxxxxx	xxx	xx.x – xx.x	xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
				xxxxxxx	YYYY-MM-DD/HH:MM	xx.x	H	1	No
				xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
KW-0761									
xxx-xxx	xxxxxxxxxxxxxx	xxx	xx.x – xx.x	xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
				xxxxxxx	YYYY-MM-DD/HH:MM	xx.x	H	2	No
				xxxxxxxx	Not Done				
	xxxxxxxxxxxxxx	xxx	xx.x – xx.x	xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			
				xxxxxxx	YYYY-MM-DD/HH:MM	xx.x	H	1	No
				xxxxxxxx	YYYY-MM-DD/HH:MM	xx.x			

Note: CS = clinically significant. CTCAE grade is assigned for selected parameters based on NCI CTCAE criteria (version 4.0).
* H = above upper limit of normal reference range; L = below lower limit of normal reference range.

The following listings will have similar layout as Listing 16.2.8.1:

Listing 16.2.8.2
Laboratory Assessment During During Pre-Treatment and Randomized Treatment Period – Hematology

Listing 16.2.8.3
Laboratory Assessment During During Pre-Treatment and Randomized Treatment Period – Coagulation Profile

Listing 16.2.8.4
Laboratory Assessment During During Pre-Treatment and Randomized Treatment Period – Thyroid Function Test

Listing 16.2.8.5
Laboratory Assessment During During Pre-Treatment and Randomized Treatment Period – T-cell Counts

Listing 16.2.8.6
Laboratory Assessment During During Pre-Treatment and Randomized Treatment Period - Urinalysis

Trt Arm Subject	Test	Visit	Urine Sample Collected	Sample Date/Time	Result	Any CS Result?
Vorinostat						
xxx-xxx	xxxxxxxxx	xxxxxxx	Yes	YYYY-MM-DD/HH:MM	xxxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxxx	No
		xxxxxxx	Yes	YYYY-MM-DD/HH:MM	xxxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxxx	No
xxx-xxx	xxxxxxxxx	xxxxxxx	Yes	YYYY-MM-DD/HH:MM	xxxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxxx	No
		xxxxxxx	Yes	YYYY-MM-DD/HH:MM	xxxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxxx	No
xxx-xxx	xxxxxxxxxx	xxxxxxx	Yes	YYYY-MM-DD/HH:MM	xxxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxxx	No
		xxxxxxx	Yes	YYYY-MM-DD/HH:MM	xxxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxxx	No
KW-0761						
xxx-xxx	xxxxxxxxxx	xxxxxxx	Yes	YYYY-MM-DD/HH:MM	xxxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxx	No
				YYYY-MM-DD/HH:MM	xxxxxxxx	No

Note: CS = clinically significant.

Listing 16.2.8.7
Laboratory Assessment During During Pre-Treatment and Randomized Treatment Period – Pregnancy Test

Trt Arm Subject	Pregnancy Test Performed?	Date Performed	Type of Test	Result
Vorinostat				
xxx-xxx	Yes	YYYY-MM-DD	Urine	xxxxxxx
	Yes	YYYY-MM-DD	Serum	xxxxxxx
	Yes	YYYY-MM-DD	Urine	xxxxxxx
xxx-xxx	Yes	YYYY-MM-DD	Urine	xxxxxxx
	No			
	Yes	YYYY-MM-DD	Serum	xxxxxxx
KW-0761				
xxx-xxx	Yes	YYYY-MM-DD	Urine	xxxxxxx
	No			
	Yes	YYYY-MM-DD	Urine	xxxxxxx

The following listings will have similar layout as Listings 16.2.8.1 to 16.2.8.7:

Listing 16.2.8.8
Laboratory Assessment During Crossover Portion – Chemistry
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.9
Laboratory Assessment During Crossover Portion – Hematology
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.10
Laboratory Assessment During Crossover Portion – Thyroid Function Test
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.11
Laboratory Assessment During Crossover Portion – T-cell Counts
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.12
Laboratory Assessment During Crossover Portion – Coagulation Profile
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.13
Laboratory Assessment During Crossover Portion – Urinalysis
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.14
Laboratory Assessment During Crossover Portion – Pregnancy Test
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.15
Laboratory Assessment – Virus Testing

Trt Arm Subject	Sample Collected?	Date/Time of Sample	HBsAG	HBcAB-IgM	HC Ab	HIV	HTLV-1
Vorinostat							
xxx-xxx	Yes	YYYY-MM-DD/HH:MM	negative	negative	negative	negative	negative
xxx-xxx	Yes	YYYY-MM-DD/HH:MM	negative	positive	negative	negative	negative
KW-0761							
xxx-xxx	Yes	YYYY-MM-DD/HH:MM	negative	negative	negative	negative	negative
xxx-xxx	Yes	YYYY-MM-DD/HH:MM	negative	negative	negative	negative	negative

Listing 16.2.8.16
Vital Signs During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Assessment Date/Time	Time Point*	Height (cm)	Weight (kg)	Blood Pressure SBP/DBP (mmHg)	Pulse Rate (bpm)	Temperature (C)	Respiratory Rate (rpm)
Vorinostat									
xxx-xxx	xxxxxxxxxx	YYYY-MM-DD/HH:MM		xxx	xx.x	xxx/xxx	xx	xx.x	xx
	xxxxxxxxxx	YYYY-MM-DD/HH:MM			xx.x	xxx/xxx	xx	xx.x	xx
	xxxxxxxxxx	YYYY-MM-DD/HH:MM				xxx/xxx	xx	xx.x	xx
	xxxxxxxxxx	YYYY-MM-DD/HH:MM				xxx/xxx	xx	xx.x	xx
KW-0761									
xxx-xxx	xxxxxxxxxx	YYYY-MM-DD/HH:MM		xxx	xx.x	xxx/xxx	xx	xx.x	xx
	xxxxxxxxxx	YYYY-MM-DD/HH:MM	1		xx.x	xxx/xxx	xx	xx.x	xx
		YYYY-MM-DD/HH:MM	2			xxx/xxx	xx	xx.x	xx
		YYYY-MM-DD/HH:MM	3			xxx/xxx	xx	xx.x	xx

* Time point: 1 = Pre-infusion, 2 = end of infusion, 3 = 1 hour post-infusion.

The following listing will have a similar layout as Listing 16.2.8.16:

Listing 16.2.8.17
Vital Signs During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.18
Electrocardiogram During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Date/Time Performed	Heart Rate (bpm)	PR (msec)	QRS (msec)	QT (msec)	QTcB (msec)	QTcF (msec)	Rhythm	Overall Interpretation
Vorinostat										
xxx-xxx	xxxxxxxx	YYYY-MM-DD/HH:MM	xxx	xxx	xxx	xxx	xxx	xxx	xxxxxx	Normal
	xxxxxxxx	YYYY-MM-DD/HH:MM	xxx	xxx	xxx	xxx	xxx*	xxx*	xxxxxx	Abnormal, NCS
	xxxxxxxx	YYYY-MM-DD/HH:MM	xxx	xxx	xxx	xxx	xxx*	xxx*	xxxxxx	Abnormal, CS
xxx-xxx	xxxxxxxx	YYYY-MM-DD/HH:MM	xxx	xxx	xxx	xxx	xxx	xxx	xxxxxx	Normal
	xxxxxxxx	YYYY-MM-DD/HH:MM	xxx	xxx	xxx	xxx	xxx	xxx	xxxxxx	Normal
KW-0761										
xxx-xxx	xxxxxxxx	YYYY-MM-DD/HH:MM	xxx	xxx	xxx	xxx	xxx	xxx	xxxxxx	Normal
	xxxxxxxx	YYYY-MM-DD/HH:MM	xxx	xxx	xxx	xxx	xxx	xxx	Other:x xxxxx	Normal

Note: for QTcB and QTcF: * = >450, ** = >480, *** = >500 msec. CS = clinically significant, NCS = not clinically significant.

The following listing will have a similar layout as Listing 16.2.8.18:

Listing 16.2.8.19
Electrocardiogram During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.20
ECOG Performance Status During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Date of Evaluation	ECOG Performance Status
Vorinostat			
xxx-xxx	xxxxxxxxx	YYYY-MM-DD	x
	xxxxxxxxx	YYYY-MM-DD	x
	xxxxxxxxx	Not Done	
	xxxxxxxxx	YYYY-MM-DD	x
KW-0761 1.0 mg/kg			
xxx-xxx	xxxxxxxxx	YYYY-MM-DD	x
	xxxxxxxxx	YYYY-MM-DD	x
	xxxxxxxxx	YYYY-MM-DD	x

The following listing will have a similar layout as Listing 16.2.8.20:

Listing 16.2.8.21
ECOG Performance Status During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.22
Physical Examination During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Physical Exam Performed?	Date Performed	Findings*	Any Changes Since Previous Exam?
Vorinostat					
xxx-xxx	xxxxxxxxx	Yes	YYYY-MM-DD	Abnormal, not CS	
	xxxxxxxxx	Yes	YYYY-MM-DD		No
	xxxxxxxxx	Yes	YYYY-MM-DD		Yes, not CS
KW-0761					
xxx-xxx	xxxxxxxxx	Yes	YYYY-MM-DD	Normal	
	xxxxxxxxx	Yes	YYYY-MM-DD		No
	xxxxxxxxx	Yes	YYYY-MM-DD		No

Note: CS = clinically significant.
* Only applies to pre-treatment visit.

The following listing will have a similar layout as Listing 16.2.8.22:

Listing 16.2.8.23
Physical Examination During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.24
Natural Ligands (MDC/TARC) Assessment During During Pre-Treatment and Randomized Treatment Period

Trt Arm Subject	Visit	Sample Collected?/ Reason Not Collected	Sample Date	MDC (ng/L)	TARC (ng/L)
Vorinostat					
xxx-xxx	xxxxxx	Yes	YYYY-MM-DD	xxxxxxxx	xxxxxxxx
	xxxxxx	No/xxxxxxxxx			
	xxxxxx	Yes	YYYY-MM-DD	xxxxxxxx	xxxxxxxx
KW-0761					
xxx-xxx	xxxxxx	Yes	YYYY-MM-DD	xxxxxxxx	xxxxxxxx
	xxxxxx	No/xxxxxxxxx			
	xxxxxx	Yes	YYYY-MM-DD	xxxxxxxx	xxxxxxxx

The following listing will have a similar layout as Listing 16.2.8.24:

Listing 16.2.8.25
Natural Ligands (MDC/TARC) Assessment During Crossover Portion
Subjects Who Are Randomized to Vorinostat and Crossed Over to KW-0761

Listing 16.2.8.26
Saliva Sample for Genetic Analysis – KW-0761 Treatment Only

Trt Arm Subject	Sample Collected?/ Reason Not Collected	Sample Date	Result
KW-0761			
xxx-xxx	Yes	YYYY-MM-DD	xxxxxxx
xxx-xxx	No/xxxxxxxxx		
xxx-xxx	Yes	YYYY-MM-DD	xxxxxxxxxx

Listing 16.2.8.27
Anti-KW-0761 Antibody Response
Subjects Exposed to KW-0761

Trt Arm / Subject	Visit	Sample Collected?/ Reason Not Collected	Sample Date	Assay – Anti KW-0761 Antibody					Neutralizing	KW-0761 Concentration (ng/mL)
				Screening	Confirmatory	Result	Status*	Titer	Result	
Initially Randomized to KW-0761										
xxx-xxx	Pre-Trt	Yes	YYYY-MM-DD	xxxxxxxx	xxxxxxxx	xxxx	xxxx	xxxx		
	End of Cycle 1	No/xxxxxxxxx								
	End of Cycle x	Yes	YYYY-MM-DD	xxxxxxxx	xxxxxxxx	xxxx	xxxx	xxxx		
	.									
	.									
	End of Treatment	Yes	YYYY-MM-DD							
xxx-xxx	Pre-Trt	Yes	YYYY-MM-DD	xxxxxxxx	xxxxxxxx	xxxx	xxxx	xxxx		
	End of Cycle 1	No/xxxxxxxxx								
	End of Cycle x	Yes	YYYY-MM-DD	xxxxxxxx	xxxxxxxx	xxxx	xxxx	xxxx		
	.									
	.									
	End of Treatment	Yes	YYYY-MM-DD	xxxxxxxx	xxxxxxxx	xxxx	xxxx	xxxx		
Cross Over to KW-0761										

Note: When Anti-KW-0761 antibody result is positive (the sample is positive in both screening assay and confirmatory assay), titer will be measured; - = not applicable or not evaluated; ** = calculated mean.
[1] Visit (cycle number) is continuous of initial treatment for subject who crossed over.
* Inconclusive because the sample is negative in screening assay and KW-0761 concentration is higher than drug tolerance limit (16000 ng/mL) or KW-0761 concentration is not determined.

Listing 16.2.8.28
Anti-KW-0761 Antibody Response for Subjects with Infusion Reactions
Subjects Exposed to KW-0761

Trt Arm Subject	Adverse Event Reported	Grade	Onset Date/ Study Day	Duration (Days)	Discontinued or Dose Interrupted?	Assay Positive at Any Time Post-Baseline Anti KW-0761 Antibody Result	 Neutralizing Result
Initially Randomized to KW-0761							
xxx-xxx	Infusion Reaction	1	YYYY-MM-DD/xx	4	No	Yes	No
	xxxxxxxxx	2	YYYY-MM-DD/xx	2	Yes		
xxx-xxx	Infusion Reaction	1	YYYY-MM-DD/xx	1	No	Yes	No
Crossed Over to KW-0761							

Study day is calculated using start of adverse event - date of first dose of study medication + 1. Duration is calculated as stop date of adverse event - start date of adverse event + 1.

Listing 16.2.8.29
CCR4 Expression

Trt Arm Subject	Visit	Sample Submitted?	Biopsy Type	Collection Date	Date Sent to Central Lab	Result
Vorinostat						
	xxxxxx	Yes	Fresh:xxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxx
xxx-xxx			xxxxx			
	xxxxxx	Yes	Archived:xxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxx
xxx-xxx			xxxxxxxx			
xxx-xxx	xxxxxx	Yes	xxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxx
KW-0761						
xxx-xxx	xxxxxx	Yes	xxxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxx
xxx-xxx	xxxxxx	Yes	xxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxx
xxx-xxx	xxxxxx	Yes	xxxxxxxxxxxxx	YYYY-MM-DD	YYYY-MM-DD	xxxxxx

Listing 16.2.8.30
General Comments

Trt Arm Subject	Visit	Cycle/Day	Page Name	Comment
Vorinostat				
xxx-xxx	xxxxxx	xx/xx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxx	xx/xx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxx	xx/xx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx
KW-0761				
xxx-xxx	xxxxxx	xx/xx	xxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxx	xx/xx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	xxxxxx	xx/xx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx