ADDENDUM
STATISTICAL ANALYSIS PLAN
(Protocol No. ASN100-201)

A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Safety and Efficacy of a Single Dose of ASN100 for the Prevention of *Staphylococcus aureus* Pneumonia in Heavily Colonized, Mechanically Ventilated Subjects

DEVELOPMENT PHASE: 2

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CONFIDENTIAL

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1. LIST OF ABBREVIATIONS

AE	Adverse event
ALT	Alanine aminotransferase
ALP	Alkaline phosphatase
ASN-1	Broadly cross-reactive anti-toxin monoclonal antibody that targets alpha-hemolysin (Hla) and 3 F-components (HlgB, LukF, LukD) involved in forming 4 of the 5 bi-component leukocidins of *Staphylococcus aureus*
ASN-2	Anti-toxin monoclonal antibody that targets the fifth bi-component leukocidin of *Staphylococcus aureus*, LukGH
ASN100	A combination of the 2 fully human monoclonal antibodies ASN-1 and ASN-2
AST	Aspartate aminotransferase
ATC	Anatomical therapeutic chemical
BMI	Body mass index
CSR	Clinical study report
ETA	Endotracheal aspirate
HABP	Hospital-acquired bacterial pneumonia
ICF	Informed consent Form
ICU	Intensive care unit
ITT	Intent-to-Treat
LLN	Lower limit of normal
MedDRA	Medical Dictionary for Regulatory Activities
MITT	Modified Intent-to-Treat
POP	Population and outcome plan
PP	Per Protocol
PT	Preferred term
S. aureus	*Staphylococcus aureus*
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SDO	Sponsor-defined outcome
SOC	System organ class
TEAE	Treatment-emergent adverse event
TFLs	Tables, figures, and listings
ULN	Upper limit of normal

VABP	Ventilator-associated bacterial pneumonia
WHO	World Health Organization

2. INTRODUCTION

This Addendum to the Statistical Analysis Plan (SAP) describes the final selected analyses and reporting based on the final SAP (dated June 25, 2018, Version 1.0), and as outlined in appendix Section 5, the final tables, figures, and listings (TFLs) shells. The purpose of this Addendum is to outline the subset of analyses to support the completion of the Clinical Study Report (CSR) for Protocol ASN100-201.

3. STUDY METHODS

3.1. Analysis Populations

The following analysis populations will be used for analyses.

3.1.1. Intent-to-Treat Population (ITT)

The ITT Population includes all subjects who are randomized to receive study drug.

3.1.2. Modified Intent-to-Treat Population (MITT)

The MITT Population includes all subjects in the ITT Population who receive study drug and who are heavily colonized with *S. aureus* as determined by quantitative or semi-quantitative culture of an ETA specimen. Exclusion from the MITT Population will be determined programmatically for each ITT subject. Programmatically determined assignment into the MITT Population will be evaluated for confirmation or Sponsor Override as applicable during a Review Meeting of the Population and Outcome Plan (POP) Review Group, as described in the POP.

Review Meetings will be held on a regular basis throughout the conduct of the study. The number of subjects included in each Review Meeting will vary depending on the number of subjects included in a data review cycle per the Medpace Rolling Data Lock Plan.

The final MITT Population classification will be performed in a blinded fashion and prior to final database lock and unblinding. After the Review Group's review, any Sponsor overrides of the MITT Population flags will be finalized and documented. The MITT Population flags will be included in the analysis datasets.

3.1.3. Per Protocol (PP) Population

The PP Population includes all subjects in the MITT Population who also meet the following criteria:

- Did not have any major protocol violations that would affect assessment of efficacy based on medical review of available data;
- Randomized in a timely manner following collection of an ETA specimen showing heavy *S. aureus* colonization;
- Was mechanically ventilated at randomization;
- Had an appropriate chest image performed at randomization;
- Did not have a change of oxygenation and onset of purulent secretions at randomization;
- Was not diagnosed with pneumonia at randomization or within 24 hours of receiving study drug;
- Received an adequate dose of study drug administered in a timely manner following study drug preparation,

- Did not die within 24 hours of receiving study drug;
- Did not have Investigator Diagnosis of Pneumonia within 24 hours of receiving study drug; and
- Complete an adequate number of Monitoring Period assessments through Day 22 based on medical review of available data.

Exclusion from the PP Population will be determined programmatically for each MITT subject. Programmatically determined assignment into the PP Population will be evaluated for confirmation or Sponsor Override as applicable during a Review Meeting.

The final PP Population classification will be performed in a blinded fashion and prior to final database lock and unblinding. After the Review Group's review, any Sponsor Overrides of the PP Population flags will be finalized and documented. The PP Population flags will be included in the analysis datasets.

3.1.4. Safety Population

The Safety Population includes all subjects who receive any amount of study drug and have at least 1 post-treatment safety assessment.

3.2. Subject Disposition

Subject disposition will be summarized for the ITT Population for each treatment group and in total. The following subject disposition categories will be included in the summary for the ITT Population:

- Subjects who randomized in primary prevention study,
- Subjects who randomized in treatment sub-study,
- Subjects who received any study drug,
- Subjects who completed the study assessments through Day 22,
- Subjects who did not complete the study assessments through Day 22,
- Subjects who completed the study assessments through Day 90,
- Subjects who did not complete the study assessments through Day 90, and
- Subjects who completed assessments through Day 22, but did not complete the study assessments through Day 90.

For subjects who did not complete the study assessments through Day 90, a summary will be provided by reason of discontinuation. In addition, the total number of subjects for each defined population will be tabulated.

3.3. Demographic and Baseline Characteristics

Demographic information including sex, race, ethnicity, corrected randomization stratification factor (receipt or non-receipt of concomitant anti-staphylococcal antibiotics at the time of randomization that are potentially active against *S. aureus* pneumonia), age

(as a continuous variable and categorized as <55, 55 - <65, 65 - <75 and ≥75 years, and categorized as <50, 50 - <65, and ≥65 years), height, weight, and BMI (as a continuous variable, categorized as <25, 25 - <30, 30 - <35, and ≥35 kg/m2), type of hospital unit at time of ICF (ICU and non-ICU), type of ICU, Length of stay (total days) in ICU post-treatment, Length of stay in ICU post-treatment category (<5, 5-12, >12 - 22, and >22 days), Acute kidney injury status at Day 2 visit, baseline creatinine (as a continuous variable and categorized as <2 and ≥2 mg/dL), and reason for mechanical ventilation (trauma, cardiovascular impairment, neurological impairment, pulmonary impairment, and other) will be summarized by treatment group for the ITT, MITT, PP, and Safety Populations.

3.4. Prior and Concomitant Medications/Procedures

Prior and concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary (Sept 2016E B2). Concomitant procedures will be coded using the Medical Dictionary for Regulatory Activities (MedDRA, Version 19.1).

Prior medications are medications used before the initiation of study drug administration. Any medications used on or after the initiation of study drug administration will be included as concomitant medications. Hence medications ongoing at start of study medication will be counted as both prior and concomitant medication.

The number and percentage of subjects taking concomitant medications will be summarized for the ITT Population by anatomic therapeutic chemical (ATC) class and preferred term for each treatment group and overall.

Prior and concomitant medications/procedures will be listed by subject.

3.5. Analysis of Efficacy

For all efficacy analyses, subjects will be analyzed in the treatment group to which they were randomized.

Sponsor defined outcomes were determined based on the review of microbiology results from samples tested at the central laboratory. In cases where a sample was not sent to the central laboratory, the determination was based on results from samples tested at the local microbiology laboratory. In all cases where both a local and central result were available, concordance was confirmed in terms of *Staphylococcus aureus*. Therefore, the study analysis utilized local microbiology data in order to utilize a more complete dataset.

3.5.1. Primary Efficacy Endpoint

The primary efficacy endpoint is whether the subject has or has not developed *S. aureus* pneumonia up to, but not including, Day 22 in the MITT Population. For the primary analysis, whether the subject has or has not developed *S. aureus* pneumonia will be based on sponsor defined outcome (SDO1).

The primary analysis is based on comparing two proportions of subjects who develop *S. aureus* pneumonia by SDO1 up to, but not including, Day 22. For each arm, the empirical proportion is defined by a ratio, which is the number of *S. aureus* pneumonia events divided

by the total number of subjects in the arm. The inference about the difference of two population rates is based on the empirical counterpart. Specifically, the point estimate, 95% confidence interval and p-value for the rate difference. If subjects discontinued from the study due to any cause prior to Day 22, it will be considered as not developing *S. aureus* pneumonia by SDO1 for the primary efficacy analysis.

3.5.2. Additional Analyses for *S. aureus* Pneumonia

Analyses of the primary efficacy endpoint will also be performed based on the PP Populations.

The following additional analyses will be performed in the MITT and PP Populations:

- The primary efficacy analysis, based on comparing two proportions of subjects who develop *S. aureus* pneumonia by SDO2 up to, but not including, Day 22. If subjects discontinued from the study due to any cause prior to Day 22 it will be considered as not developing *S. aureus* pneumonia for this analysis by SDO2.
- The additional analysis is based on comparing two proportions of subjects who develop *S. aureus* pneumonia by SDO1 and SDO2 up to, but not including, Day 22. For each arm, the empirical proportion is defined by a ratio, which is the number of *S. aureus* pneumonia events divided by the total number of subjects in the arm. The inference about the difference of two population rates is based on the empirical counterpart. Specifically, the point estimate, 95% confidence interval and p-value for the rate difference. If subjects discontinued from the study due to any cause prior to Day 22, data will be analyzed both as assumed to have developed *S. aureus* pneumonia and not having developed *S. aureus* pneumonia by SDO1 and SDO2.
- The Kaplan-Meier analysis will be performed for the proportion of subjects who develop *S. aureus* pneumonia by Day 21 as determined by SDO1 and SDO2. The proportion of subjects who develop *S. aureus* pneumonia up to but not including Day 22 will be obtained from Kaplan-Meier estimates for each treatment group. The number and percentage of subjects who developed *S. aureus* pneumonia or were censored will be summarized. The Kaplan-Meier estimate of event rates evaluated at Day 21 and the corresponding 95% confidence intervals will be presented for each treatment group. Subjects who did not develop *S. aureus* pneumonia, discontinued from the study, or died prior to Day 22 will be considered censored. For the censored subjects, the last assessment date on which the subject did not develop *S. aureus* pneumonia based on the Investigator's assessment will be used as the date of censoring.
- The additional Kaplan-Meier analysis will be performed for the proportion of subjects who develop *S. aureus* pneumonia by Day 21 as determined by SDO1 and SDO2. The proportion of subjects who develop *S. aureus* pneumonia up to but not including Day 22 will be obtained from Kaplan-Meier estimates for each treatment group. The number and percentage of subjects who developed *S. aureus* pneumonia or were censored will be summarized. The Kaplan-Meier estimate of event rates evaluated at Day 21 and the corresponding 95% confidence intervals will be

presented for each treatment group. Discontinuation from the study due to any cause up to but not including Day 22 will be considered as an 'Event'.

- The Kaplan-Meier analysis will be performed for the proportion of subjects who develop *S. aureus* pneumonia up to but not including Day 22 as determined by the Investigator's judgement and the Review Meeting's determination of *S. aureus* as a causative pneumonia pathogen.

The number and percentage of subjects with SDO1 and SDO2 of *S. aureus* pneumonia, no *S. aureus* pneumonia, indeterminate, and censored in each treatment group will be summarized descriptively.

3.5.3. Secondary Efficacy Endpoints

Duration of mechanical ventilation and length of hospital ICU stay during the first 21 days post-randomization will be summarized descriptively and compared between treatment groups using a Wilcoxon rank sum test in the MITT and PP Populations.

The other secondary endpoint, 28-day all-cause mortality in the MITT and PP Population, will be descriptively summarized by treatment group. All-cause mortality rate at Day 28 based on Kaplan-Meier estimates along with the 95% confidence interval will also be presented for each treatment group. Subjects whose survival status are unknown due to early termination or who are lost to follow up will be censored at the last day the subject was known to be alive.

3.5.4. Exploratory Efficacy Endpoints

Exploratory efficacy endpoints include:

- Proportion of subjects in the MITT and PP Populations with a diagnosis of HABP >48 hours post-extubation up to, but not including, Day 22 in extubated subjects;
- Proportion of subjects in the MITT and PP Populations with development of VABP up to, but not including, Day 22;
- Incidence of all pneumonias (SDO1 and SDO2) up to, but not including, Day 22 in the MITT and PP Populations, data will be analyzed both as assumed to have developed pneumonia and not having developed pneumonia by SDO1 and SDO2;
- Incidence of all bacterial pneumonias (SDO1 and SDO2) up to, but not including, Day 22 in the MITT and PP Populations, data will be analyzed both as assumed to have developed bacterial pneumonia and not having developed bacterial pneumonia by SDO1 and SDO2;
- Incidence of other non-*S. aureus* pneumonias (SDO1 and SDO2) up to, but not including, Day 22 in the MITT and PP Populations, data will be analyzed both as assumed to have developed non-*S. aureus* pneumonia and not having developed non-*S. aureus* pneumonia by SDO1 and SDO2 ;
- Incidence of Gram negative pneumonias (SDO1 and SDO2) up to, but not including, Day 22 in the MITT and PP Populations, data will be analyzed both as

assumed to have developed Gram negative pneumonia and not having developed Gram negative pneumonia by SDO1 and SDO2;

- Incidence of other *S. aureus* (Non-Pulmonary *S. aureus*) infections acquired up to, but not including, Day 22 in the MITT and PP Populations.
- Summary of all-cause mortality rate through entire study period (through Day 90) in the MITT and PP Populations.

All exploratory efficacy endpoints will be descriptively summarized by treatment group.

3.6. Subgroup Analyses

The following subgroups will be used for subgroup analyses for the primary efficacy endpoint in the MITT Population, i.e. whether the subject has or doesn't have of *S. aureus* pneumonia up to, but not including, Day 22 for both SDO1 and SDO2 populations.

- Corrected randomization stratification (Receipt or Non-Receipt of concomitant anti-staphylococcal antibiotics at the time of randomization that are potentially active against *S. aureus* pneumonia.)
- Type of ICU (e.g., SICU, MICU, Neuro ICU, Trauma ICU)
- Length of stay in the intensive care unit (ICU) post-treatment (<5, 5-12, >12-22, and >22 days)
- Reason for mechanical ventilation
- BMI categories: <25, 25-<30, 30-<35, and ≥35
- Age: <50, 50-<65, and >65
- Male vs. female
- Acute kidney injury defined by an absolute increase in serum creatinine of 0.3 mg/dL or a 50% increase (*viz.*, 0.3 mg/dL increase if baseline ≥0.6 mg/dL and 50% increase if baseline is ≤0.6 mg/dL) within 48 hours from receipt of study drug
- Presence of renal disease at Baseline: serum creatinine <2 mg/dL and ≥2 mg/dl.

The subgroup analyses for all-cause mortality rate at Day 28 and mortality rate through entire study period (through Day 90) will be performed by country in the MITT Population.

In addition, duration of mechanical ventilation and length of hospital ICU stay during the first 21 days post-randomization will be performed by the following subgroups in the MITT Population. Data will be analyzed both as assumed to have developed the following pneumonia and not having developed the following pneumonia by SDO1 and SDO2:

- All pneumonia (SDO1)
- All pneumonia (SDO2)
- *S. aureus* pneumonia (SDO1)
- *S. aureus* pneumonia (SDO2)

- All bacterial pneumonia (SDO1)
- All bacterial pneumonia (SDO2)
- Non-*S. aureus* pneumonia (SDO1)
- Non-*S. aureus* pneumonia (SDO2)
- Gram negative pneumonia (SDO1)
- Gram negative pneumonia (SDO2)

3.7. Analysis of Safety Data

All subjects in the Safety Population will be included in the safety analyses and analyzed based on the actual treatment received.

3.7.1. Adverse Events

Verbatim descriptions of Adverse Events (AEs) will be coded using Version 19.1 of MedDRA. Summary tables will be provided for all Treatment-Emergent Adverse Events (TEAEs). A TEAE is defined as an AE with a start date and time on or after the initiation of study drug administration. If the time of an AE is missing, it is considered treatment emergent if it starts on the same date as the initiation of study drug administration. All AEs (including non-TEAEs), Serious AEs (SAEs), and AEs leading to study drug discontinuation will be provided in listings by treatment group, subject ID, verbatim term, MedDRA system organ class (SOC) and preferred term (PT), start and end date, seriousness flag, severity, relationship to study drug, and action taken with study drug.

An overall summary of AEs will include the number and percentage of subjects in each treatment group who experienced at least one AE/TEAE in the following categories: any AE, any TEAE, any drug-related TEAE, any severe TEAE, any SAE, any drug-related SAE, any SAE leading to death, any TEAE leading to discontinuation of study drug, and any SAE leading to study drug discontinuation. Subjects with multiple events will be counted only once within each category. Severity grade and relationship will be counted using the maximum severity and the strongest relationship respectively for a subject with multiple TEAEs.

The number and percentage of subjects reporting a TEAE in each treatment group will be tabulated by SOC and PT; by SOC, PT, and severity; and by SOC, PT, and relationship (unrelated or related to study drug). For all analyses of TEAEs, if the same AE (based on PT) is reported for the same subject more than once, the AE is counted only once for that PT and at the highest severity and strongest relationship to study drug.

The number and percentage of subjects reporting a treatment-emergent SAE in each treatment group will be summarized by SOC and PT.

Listings will be provided for SAEs and AEs leading to drug discontinuation. In addition, all AEs will be listed.

3.7.2. Vital Signs

Vital sign measurements will include temperature, systolic and diastolic blood pressure, pulse, respiratory rate, and oxygenation status (as measured by pulse oximetry or arterial blood gas).

Descriptive statistics will be used to summarize vital signs measurements and change from baseline by each scheduled time point.

All vital sign assessments will be listed by subject.

3.7.3. Clinical Laboratory Tests

Descriptive statistics will be provided for hematology, chemistry, urinalysis, and coagulation parameters and change from baseline by each scheduled time point.

Shift tables from baseline to the worst post-baseline value will be provided for selected chemistry parameters (Alanine aminotransferase, Aspartate aminotransferase, Total Bilirubin, Creatinine, and Alkaline phosphatase) and hematology parameters (Hematocrit, Hemoglobin, Platelets, White blood cell count and differential). Both scheduled and unscheduled visits will be considered. For chemistry parameters, the following categories will be used: <LLN, normal, >ULN and ≤3×ULN, >3×ULN to ≤5×ULN, >5×ULN, and missing. For hematology parameters, the following categories will be used: low, normal, high, and missing.

The number and percentage of subjects with the following PCS abnormal liver function test will be summarized:

- ALT ≥3×ULN and ≥5×ULN
- AST ≥3×ULN and ≥5×ULN
- ALT or AST ≥3×ULN and ≥5×ULN
- Total bilirubin ≥1.5×ULN and ≥2×ULN
- ALP ≥1.5×ULN and ≥3×ULN
- ALT or AST ≥3×ULN and Total bilirubin ≥2×ULN
- Potential Hy's Law cases: ALT or AST ≥3×ULN, Total bilirubin ≥2×ULN, and ALP ≤ 2×ULN

A listing of subjects with any post-baseline abnormal liver function tests will be presented.

All clinical laboratory data will be listed. Values outside the normal ranges will be flagged.

4. GENERAL INFORMATION

4.1. Statistical Software

The creation of analysis datasets and statistical analyses will be done using SAS® version 9.3 or higher. The Medpace standard operating procedures (Medpace documents GL-DS-02-S2.1 and GL-DS-03-S1) will be followed for the validation of all SAS programs and outputs.

4.2. Format of Tables, Listings, and Figures

The format of tables, listings, and figures will be described in a stand-alone programming specifications document and will be finalized before database lock for the study.

5. APPENDIX

Table Mock-Ups

Arsanis, Inc. Program Name: XXXX.sas
Protocol Number: ASN100-201 Run Date: MM/DD/YYYY HH:MM
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Table 14.1.1.1
Subject Disposition
Intent-to-Treat Population

	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Total (N=###) n (%)
Subjects who randomized in primary prevention study	### (###.#)	### (###.#)	### (###.#)
Subjects who randomized in treatment sub-study [1]	### (###.#)	### (###.#)	### (###.#)
Subjects who received study drug	### (###.#)	### (###.#)	### (###.#)
Subjects who completed the study assessments through Day 22	### (###.#)	### (###.#)	### (###.#)
Subjects who did not complete the study assessments through Day 22	### (###.#)	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] A single subject 268-002-118 was enrolled and randomized into the treatment sub-study. This subject is only included in tabulations presenting disposition and safety data.

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Table 14.1.1.1
Subject Disposition
Intent-to-Treat Population

	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Total (N=###) n (%)
Subjects who completed the study assessments through Day 90	### (###.#)	### (###.#)	### (###.#)
Subjects who did not complete the study assessments through Day 90	### (###.#)	### (###.#)	### (###.#)
Adverse event	### (###.#)	### (###.#)	### (###.#)
Death	### (###.#)	### (###.#)	### (###.#)
Lost to follow-up	### (###.#)	### (###.#)	### (###.#)
Non-compliance with study drug	### (###.#)	### (###.#)	### (###.#)
Physician decision	### (###.#)	### (###.#)	### (###.#)
Protocol deviation	### (###.#)	### (###.#)	### (###.#)
Withdrawal of consent by LAR	### (###.#)	### (###.#)	### (###.#)
Withdrawal of consent by subject	### (###.#)	### (###.#)	### (###.#)
Discontinuation by subject	### (###.#)	### (###.#)	### (###.#)
Discontinuation by LAR	### (###.#)	### (###.#)	### (###.#)
Other	### (###.#)	### (###.#)	### (###.#)
Subjects who completed assessments through Day 22, but did not complete the study assessments through Day 90	### (###.#)	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] A single subject 268-002-118 was enrolled and randomized into the treatment sub-study. This subject is only included in tabulations presenting disposition and safety data.

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Table 14.1.1.2
Analysis Populations
Intent-to-Treat Population

	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Total (N=###) n (%)
Intent-to-Treat (ITT) Population [1]	### (###.#)	### (###.#)	### (###.#)
Modified Intent-to-Treat (MITT) Population [2]	### (###.#)	### (###.#)	### (###.#)
Per Protocol (PP) Population [3]	### (###.#)	### (###.#)	### (###.#)
Safety Population [4]	### (###.#)	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Intent-to-Treat Population includes all subjects who are randomized to receive study drug.
[2] Modified Intent-to-Treat Population includes subjects in the ITT Population who receive study drug and who are heavily colonized with S. aureus as determined by quantitative or semi-quantitative culture of an ETA specimen.
[3] Per Protocol Population includes all subjects in the MITT Population who also meet the criteria specified in the SAP.
[4] Safety Population includes all subjects who receive any amount of study drug and have at least 1 post-treatment safety assessment.

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Table 14.1.2.1
Summary of Demographic and Baseline Characteristics
Intent-to-Treat Population

Demographics/Characteristics Category/Statistic	ASN100 (N=###)	Placebo (N=###)	Total (N=###)
Age (years)			
n	###	###	###
Mean	##.#	##.#	##.#
Standard Deviation	##.##	##.##	##.##
Minimum	##	##	##
Median	##.#	##.#	##.#
Maximum	##	##	##
Age group 1 (n, %)			
<55 years	### (###.#)	### (###.#)	### (###.#)
55 - <65 years	### (###.#)	### (###.#)	### (###.#)
65 - <75 years	### (###.#)	### (###.#)	### (###.#)
>=75 years	### (###.#)	### (###.#)	### (###.#)
Age group 2 (n, %)			
<50 years	### (###.#)	### (###.#)	### (###.#)
50 - <65 years	### (###.#)	### (###.#)	### (###.#)
>=65 years	### (###.#)	### (###.#)	### (###.#)
Gender (n, %)			
Male	### (###.#)	### (###.#)	### (###.#)
Female	### (###.#)	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
Baseline is defined as the last measurement or assessment prior to the first and only dose of study drug.
[1] Acute kidney injury is defined as an absolute increase in serum creatinine of 0.3 mg/dL or a 50% increase (i.e., 0.3 mg/dL Increase if baseline >=0.6 mg/dL and 50% increase if baseline is <=0.6 mg/dL) within 48 hours from receipt of study drug.

Table 14.1.2.1
Summary of Demographic and Baseline Characteristics
Intent-to-Treat Population

Demographics/Characteristics Category/Statistic	ASN100 (N=###)	Placebo (N=###)	Total (N=###)
Race (n, %)			
American Indian or Alaska Native	### (###.#)	### (###.#)	### (###.#)
Asian	### (###.#)	### (###.#)	### (###.#)
Black or African American	### (###.#)	### (###.#)	### (###.#)
Native Hawaiian or other Pacific Islander	### (###.#)	### (###.#)	### (###.#)
White	### (###.#)	### (###.#)	### (###.#)
Other	### (###.#)	### (###.#)	### (###.#)
Ethnicity (n, %)			
Hispanic or Latino	### (###.#)	### (###.#)	### (###.#)
Not Hispanic or Latino	### (###.#)	### (###.#)	### (###.#)
Not reported	### (###.#)	### (###.#)	### (###.#)
Unknown	### (###.#)	### (###.#)	### (###.#)
Weight (kg)			
n	###	###	###
Mean	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###
Minimum	##.#	##.#	##.#
Median	##.##	##.##	##.##
Maximum	##.#	##.#	##.#
Height (cm)			
n	###	###	###
Mean	##.#	##.#	##.#
Standard Deviation	##.##	##.##	##.##
Minimum	##	##	##
Median	##.#	##.#	##.#
Maximum	##	##	##

Percentage is calculated using the number of subjects in the column heading as the denominator.
Baseline is defined as the last measurement or assessment prior to the first and only dose of study drug.
[1] Acute kidney injury is defined as an absolute increase in serum creatinine of 0.3 mg/dL or a 50% increase (i.e., 0.3 mg/dL Increase if baseline >=0.6 mg/dL and 50% increase if baseline is <=0.6 mg/dL) within 48 hours from receipt of study drug.

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Table 14.1.2.1
Summary of Demographic and Baseline Characteristics
Intent-to-Treat Population

Demographics/Characteristics Category/Statistic	ASN100 (N=###)	Placebo (N=###)	Total (N=###)
Body Mass Index (kg/m^2)			
n	###	###	###
Mean	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###
Minimum	##.#	##.#	##.#
Median	##.##	##.##	##.##
Maximum	##.#	##.#	##.#
Body Mass Index category (n, %)			
<25 kg/m^2	### (###.#)	### (###.#)	### (###.#)
25-<30 kg/m^2	### (###.#)	### (###.#)	### (###.#)
30-<35 kg/m^2	### (###.#)	### (###.#)	### (###.#)
>=35 kg/m^2	### (###.#)	### (###.#)	### (###.#)
Corrected randomization stratification (Receipt of concomitant anti-staphylococcal antibiotics at time of randomization that are potentially active against S. aureus pneumonia (n, %)			
Yes	### (###.#)	### (###.#)	### (###.#)
No	### (###.#)	### (###.#)	### (###.#)
Type of Hospital Unit at Time of ICF (n, %)			
ICU	### (###.#)	### (###.#)	### (###.#)
MICU - Medical ICU	### (###.#)	### (###.#)	### (###.#)
SICU - Surgical ICU	### (###.#)	### (###.#)	### (###.#)
TICU - Trauma ICU	### (###.#)	### (###.#)	### (###.#)
NICU - Neuro ICU	### (###.#)	### (###.#)	### (###.#)
CCU - Coronary Care Unit	### (###.#)	### (###.#)	### (###.#)
Other ICU	### (###.#)	### (###.#)	### (###.#)
Non-ICU	### (###.#)	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
Baseline is defined as the last measurement or assessment prior to the first and only dose of study drug.
[1] Acute kidney injury is defined as an absolute increase in serum creatinine of 0.3 mg/dL or a 50% increase (i.e., 0.3 mg/dL Increase if baseline >=0.6 mg/dL and 50% increase if baseline is <=0.6 mg/dL) within 48 hours from receipt of study drug.

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Table 14.1.2.1
Summary of Demographic and Baseline Characteristics
Intent-to-Treat Population

Demographics/Characteristics Category/Statistic	ASN100 (N=###)	Placebo (N=###)	Total (N=###)
Length of stay (total days) in ICU post-treatment			
n	###	###	###
Mean	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###
Minimum	##.#	##.#	##.#
Median	##.##	##.##	##.##
Maximum	##.#	##.#	##.#
Length of stay in ICU post-treatment category (n, %)			
<5 days	### (###.#)	### (###.#)	### (###.#)
5-12 days	### (###.#)	### (###.#)	### (###.#)
>12-22 days	### (###.#)	### (###.#)	### (###.#)
>22 days	### (###.#)	### (###.#)	### (###.#)
Acute kidney injury status at Day 2 visit (n, %) [1]			
Yes	### (###.#)	### (###.#)	### (###.#)
No	### (###.#)	### (###.#)	### (###.#)
Baseline creatinine (mg/dL)			
n	###	###	###
Mean	##.###	##.###	##.###
Standard Deviation	##.####	##.####	##.####
Minimum	##.##	##.##	##.##
Median	##.###	##.###	##.###
Maximum	##.##	##.##	##.##
Baseline creatinine category (n, %)			
<2 mg/dL	### (###.#)	### (###.#)	### (###.#)
>=2 mg/dL	### (###.#)	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
Baseline is defined as the last measurement or assessment prior to the first and only dose of study drug.
[1] Acute kidney injury is defined as an absolute increase in serum creatinine of 0.3 mg/dL or a 50% increase (i.e., 0.3 mg/dL Increase if baseline >=0.6 mg/dL and 50% increase if baseline is <=0.6 mg/dL) within 48 hours from receipt of study drug.

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Table 14.1.2.1
Summary of Demographic and Baseline Characteristics
Intent-to-Treat Population

Demographics/Characteristics Category/Statistic	ASN100 (N=###)	Placebo (N=###)	Total (N=###)
Reason for mechanical ventilation at baseline (n, %)			
Cardiovascular impairment	### (###.#)	### (###.#)	### (###.#)
Neurological impairment	### (###.#)	### (###.#)	### (###.#)
Pulmonary impairment	### (###.#)	### (###.#)	### (###.#)
Trauma	### (###.#)	### (###.#)	### (###.#)
Other	### (###.#)	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
Baseline is defined as the last measurement or assessment prior to the first and only dose of study drug.
[1] Acute kidney injury is defined as an absolute increase in serum creatinine of 0.3 mg/dL or a 50% increase (i.e., 0.3 mg/dL Increase if baseline >=0.6 mg/dL and 50% increase if baseline is <=0.6 mg/dL) within 48 hours from receipt of study drug.

The layouts of the following tables will be the same as Table 14.1.2.1:

Table 14.1.2.2
Summary of Demographic and Baseline Characteristics
Modified Intent-to-Treat Population

Table 14.1.2.3
Summary of Demographic and Baseline Characteristics
Per Protocol Population

Table 14.1.2.4
Summary of Demographic and Baseline Characteristics
Safety Population

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Table 14.1.3
Summary of Concomitant Medications
Intent-to-Treat Population

ATC Classification Preferred Term	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Total (N=###) n (%)
Any concomitant medications	### (###.#)	### (###.#)	### (###.#)
ATC Classification 1	### (###.#)	### (###.#)	### (###.#)
Preferred Term 1	### (###.#)	### (###.#)	### (###.#)
Preferred Term 2	### (###.#)	### (###.#)	### (###.#)
ATC Classification 2	### (###.#)	### (###.#)	### (###.#)
Preferred Term 1	### (###.#)	### (###.#)	### (###.#)
Preferred Term 2	### (###.#)	### (###.#)	### (###.#)

Coding is based on WHO Drug Dictionary Sept 2016E.
Percentage is calculated using the number of subjects in the column heading as the denominator.
Concomitant medications are medications used on or after the initiation of study drug administration.

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Table 14.2.1.1
Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population

SDO1	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Treatment Comparison [1] Difference (%)	95% CI	P-value
Yes	### (###.#)	### (###.#)	##.#	(##.##, ##.#)	#.####
No	### (###.#)	### (###.#)			
Censored	### (###.#)	### (###.#)			
Indeterminate	### (###.#)	### (###.#)			

Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Treatment difference (ASN100 - Placebo) is the estimate of the difference in the S. aureus pneumonias rate based on SDO1 between the two treatment arms. The difference estimates, the 95% CIs, and P-values are obtained based on Wald test on equality of proportions.
Note: In subjects who are not confirmed as having S. aureus pneumonia and who are discontinued from the study due to any cause prior to Day 22, they are considered as not developing S. aureus pneumonia.

The layout of the following table will be the same as Table 14.2.1.1:

Table 14.2.1.2
Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Per Protocol Population

Arsanis, Inc. Program Name: XXXX.sas
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Table 14.2.1.3
Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population

SDO2	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Treatment Comparison [1] Difference (%)	95% CI	P-value
Yes	### (###.#)	### (###.#)	##.#	(##.##, ##.#)	#.####
No	### (###.#)	### (###.#)			
Censored	### (###.#)	### (###.#)			
Indeterminate	### (###.#)	### (###.#)			

Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Treatment difference (ASN100 - Placebo) is the estimate of the difference in the S. aureus pneumonias rate based on SDO2 between the two treatment arms. The difference estimates, the 95% CIs, and P-values are obtained based on Wald test on equality of proportions.
Note: In subjects who are not confirmed as having S. aureus pneumonia and who are discontinued from the study due to any cause prior to Day 22, they are considered as not developing S. aureus pneumonia.

The layout of the following table will be the same as Table 14.2.1.3:

Table 14.2.1.4
Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Per Protocol Population

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Table 14.2.1.5
Additional Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population

Category	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Treatment Comparison [1] Difference (%)	95% CI	P-value
SDO1=Yes + Presumed S. aureus Pneumonia [2]	### (###.#)	### (###.#)	##.#	(##.##, ##.#)	#.####
SDO1=Yes	### (###.#)	### (###.#)			
Presumed S. aureus Pneumonia [2]	### (###.#)	### (###.#)			

Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Treatment difference (ASN100 - Placebo) is the estimate of the difference in the S. aureus pneumonias rate based on SDO1 and Presumed S. aureus pneumonia between the two treatment arms. The difference estimates, the 95% CIs, and P-values are obtained based on Wald test on equality of proportions.
[2] In subjects who are not confirmed as having S. aureus pneumonia and who are discontinued from the study due to any cause prior to Day 22, they are considered as developing S. aureus pneumonia, i.e., Presumed S. aureus pneumonia.

The layout of the following table will be the same as Table 14.2.1.5:

Table 14.2.1.6
Additional Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Per Protocol Population

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Table 14.2.1.7
Additional Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population

Category	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Treatment Comparison [1] Difference (%)	95% CI	P-value
SDO2=Yes + Presumed S. aureus Pneumonia [2]	### (###.#)	### (###.#)	##.#	(##.##, ##.#)	#.####
SDO2=Yes	### (###.#)	### (###.#)			
Presumed S. aureus Pneumonia [2]	### (###.#)	### (###.#)			

Percentage is calculated using the number of subjects in the column heading as the denominator.
[1] Treatment difference (ASN100 - Placebo) is the estimate of the difference in the S. aureus pneumonias rate based on SDO2 and Presumed S. aureus pneumonia between the two treatment arms. The difference estimates, the 95% CIs, and P-values are obtained based on Wald test on equality of proportions.
[2] In subjects who are not confirmed as having S. aureus pneumonia and who are discontinued from the study due to any cause prior to Day 22, they are considered as developing S. aureus pneumonia, i.e., Presumed S. aureus pneumonia.

The layout of the following table will be the same as Table 14.2.1.7:

Table 14.2.1.8
Additional Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Per Protocol Population

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Table 14.2.2.1
Kaplan-Meier Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population

	ASN100 (N=###) n (%)	Placebo (N=###) n (%)
Subjects with S. aureus pneumonia up to but not including Day 22	### (###.#)	### (###.#)
Subjects censored	### (###.#)	### (###.#)
Kaplan-Meier Estimate (95% CI)	##.# (##.#, ##.#)	##.# (##.#, ##.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
Note: Subjects who did not develop S. aureus pneumonia, discontinued from the study, or died prior to Day 22 will be considered censored.

The layouts of the following tables will be the same as Table 14.2.2.1:

Table 14.2.2.2
Kaplan-Meier Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Per Protocol Population

Table 14.2.2.3
Kaplan-Meier Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population

Table 14.2.2.4
Kaplan-Meier Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Per Protocol Population

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Table 14.2.2.5
Additional Kaplan-Meier Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population

	ASN100 (N=###) n (%)	Placebo (N=###) n (%)
Subjects with S. aureus pneumonia up to but not including Day 22	### (###.#)	### (###.#)
Subjects censored	### (###.#)	### (###.#)
Kaplan-Meier Estimate (95% CI)	##.# (##.#, ##.#)	##.# (##.#, ##.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
Note: Discontinuation from the study due to any cause up to but not including Day 22 will be considered as an event.

The layouts of the following tables will be the same as Table 14.2.2.5:

Table 14.2.2.6
Additional Kaplan-Meier Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Per Protocol Population

Table 14.2.2.7
Additional Kaplan-Meier Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population

Table 14.2.2.8
Additional Kaplan-Meier Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Per Protocol Population

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Table 14.2.2.9
Kaplan-Meier Analysis of S. aureus Pneumonia Up to But Not Including Day 22
Determined by Investigator's Judgement of S. aureus as a Causative Pneumonia Pathogen
Modified Intent-to-Treat Population

	ASN100 (N=###) n (%)	Placebo (N=###) n (%)
Subjects with S. aureus pneumonia up to but not including Day 22	### (###.#)	### (###.#)
Subjects censored	### (###.#)	### (###.#)
Kaplan-Meier Estimate (95% CI)	##.# (##.#, ##.#)	##.# (##.#, ##.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
Determination of S. aureus as causative pathogen was confirmed and accepted by Sponsor at review meeting.

The layouts of the following tables will be the same as Table 14.2.2.9

Table 14.2.2.10
Kaplan-Meier Analysis of S. aureus Pneumonia Up to But Not Including Day 22
Determined by Investigator's Judgement of S. aureus as a Causative Pneumonia Pathogen
Per Protocol Population

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Table 14.2.3.1.1
Subgroup Analysis - Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Corrected Randomization Stratification

Subgroup SDO1	ASN100 n/N' (%)	Placebo n/N' (%)	Treatment Comparison [1] Difference (%)	95% CI	P-value
Receipt of concomitant anti-staphylococcal antibiotics at the time of randomization that are potentially active against S. aureus pneumonia					
Yes	### (###.#)	### (###.#)	##.#	(##.##, ##.#)	#.####
No	### (###.#)	### (###.#)			
Censored	### (###.#)	### (###.#)			
Indeterminate	### (###.#)	### (###.#)			
Non-Receipt of concomitant anti-staphylococcal antibiotics at the time of randomization that are potentially active against S. aureus pneumonia					
Yes	### (###.#)	### (###.#)	##.#	(##.##, ##.#)	#.####
No	### (###.#)	### (###.#)			
Censored	### (###.#)	### (###.#)			
Indeterminate	### (###.#)	### (###.#)			

Percentage is calculated using N' which is the number of subjects in each subgroup as the denominator.
[1] Treatment difference (ASN100 - Placebo) is the estimate of the difference in the S. aureus pneumonias rate based on SDO1 at specified subgroup between the two treatment arms. The difference estimates, the 95% CIs, and P-values are obtained based on Wald test on equality of proportions.
Note: In subjects who are not confirmed as having S. aureus pneumonia and who are discontinued from the study due to any cause prior to Day 22, they are considered as not developing S. aureus pneumonia.

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Table 14.2.3.1.2
Subgroup Analysis - Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Corrected Randomization Stratification

Subgroup SDO2	ASN100 n/N' (%)	Placebo n/N' (%)	Treatment Comparison [1] Difference (%)	 95% CI	 P-value
Receipt of concomitant anti-staphylococcal antibiotics at the time of randomization that are potentially active against S. aureus pneumonia					
Yes	### (###.#)	### (###.#)	##.#	(##.##, ##.#)	#.####
No	### (###.#)	### (###.#)			
Censored	### (###.#)	### (###.#)			
Indeterminate	### (###.#)	### (###.#)			
Non-Receipt of concomitant anti-staphylococcal antibiotics at the time of randomization that are potentially active against S. aureus pneumonia					
Yes	### (###.#)	### (###.#)	##.#	(##.##, ##.#)	#.####
No	### (###.#)	### (###.#)			
Censored	### (###.#)	### (###.#)			
Indeterminate	### (###.#)	### (###.#)			

Percentage is calculated using N' which is the number of subjects in each subgroup as the denominator.
[1] Treatment difference (ASN100 - Placebo) is the estimate of the difference in the S. aureus pneumonias rate based on SDO2 at specified subgroup between the two treatment arms. The difference estimates, the 95% CIs, and P-values are obtained based on Wald test on equality of proportions.
Note: In subjects who are not confirmed as having S. aureus pneumonia and who are discontinued from the study due to any cause prior to Day 22, they are considered as not developing S. aureus pneumonia.

The layouts of the following tables will be the same as Tables 14.2.3.1.1 and 14.2.3.1.2:

Table 14.2.3.2.1
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Type of ICU at Baseline

Table 14.2.3.2.2
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Type of ICU at Baseline

Table 14.2.3.3.1
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Length of Stay in ICU Post-Treatment

Table 14.2.3.3.2
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Length of Stay in ICU Post-Treatment

Table 14.2.3.4.1
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Baseline BMI Category

Table 14.2.3.4.2
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Baseline BMI Category

Table 14.2.3.5.1
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Age Group

Table 14.2.3.5.2
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Age Group

Table 14.2.3.6.1
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Gender

Table 14.2.3.6.2
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Gender

The layouts of the following tables will be the same as Tables 14.2.3.1.1 and 14.2.3.1.2:

<<Programing note: for tables 14.2.3.7.1 and 14.2.3.7.2, add footnote "Acute kidney injury is defined as an absolute increase in serum creatinine of 0.3 mg/dL or a 50% increase (i.e., 0.3 mg/dL increase if baseline >=0.6 mg/dL and 50% increase if baseline is <=0.6 mg/dL) within 48 hours from receipt of study drug.">>

Table 14.2.3.7.1
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Acute Kidney Injury Status within 48 hours from receipt of study drug

Table 14.2.3.7.2
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Acute Kidney Injury Status within 48 hours from receipt of study drug

Table 14.2.3.8.1
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Baseline Creatinine Category

Table 14.2.3.8.2
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Baseline Creatinine Category

Table 14.2.3.9.1
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO1) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Reason for Mechanical Ventilation at Baseline

Table 14.2.3.9.2
Subgroup Analysis – Analysis of Sponsor-Defined Outcome (SDO2) of S. aureus Pneumonia Up to But Not Including Day 22
Modified Intent-to-Treat Population
By Reason for Mechanical Ventilation at Baseline

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Table 14.2.4.1.1
Summary of Pneumonia Infection Rate Up to But Not Including Day 22
Modified Intent-to-Treat Population

Category	ASN100 (N=###) n (%)	Placebo (N=###) n (%)
All pneumonia (SDO1)	### (###.#)	### (###.#)
All pneumonia (SDO2)	### (###.#)	### (###.#)
S. aureus pneumonia (SDO1)	### (###.#)	### (###.#)
S. aureus pneumonia (SDO2)	### (###.#)	### (###.#)
All bacterial pneumonia rate (SDO1)	### (###.#)	### (###.#)
All bacterial pneumonia rate (SDO2)	### (###.#)	### (###.#)
Non-S. aureus pneumonia rate (SDO1)	### (###.#)	### (###.#)
Non-S. aureus pneumonia rate (SDO2)	### (###.#)	### (###.#)
Gram negative pneumonia rate (SDO1)	### (###.#)	### (###.#)
Gram negative pneumonia rate (SDO2)	### (###.#)	### (###.#)
Non-pulmonary S. aureus infection rate	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
Note: In subjects who are not confirmed as having the specific category and who are discontinued from the study due to any cause prior to Day 22, they are considered as not developing that category.

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Table 14.2.4.1.2
Additional Summary of Pneumonia Infection Rate Up to But Not Including Day 22
Modified Intent-to-Treat Population

Category	ASN100 (N=###) n (%)	Placebo (N=###) n (%)
All pneumonia (SDO1)	### (###.#)	### (###.#)
All pneumonia (SDO2)	### (###.#)	### (###.#)
S. aureus pneumonia (SDO1)	### (###.#)	### (###.#)
S. aureus pneumonia (SDO2)	### (###.#)	### (###.#)
All bacterial pneumonia rate (SDO1)	### (###.#)	### (###.#)
All bacterial pneumonia rate (SDO2)	### (###.#)	### (###.#)
Non-S. aureus pneumonia rate (SDO1)	### (###.#)	### (###.#)
Non-S. aureus pneumonia rate (SDO2)	### (###.#)	### (###.#)
Gram negative pneumonia rate (SDO1)	### (###.#)	### (###.#)
Gram negative pneumonia rate (SDO2)	### (###.#)	### (###.#)
Non-pulmonary S. aureus infection rate	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
Note: In subjects who are not confirmed as having the specific category and who are discontinued from the study due to any cause prior to Day 22, they are considered as developing that category.

The layouts of the following tables will be the same as Table 14.2.4.1.1 and 14.2.4.1.2:

Table 14.2.4.2.1
Summary of Pneumonias Infection Rates Up to But Not Including Day 22
Per Protocol Population

Table 14.2.4.2.2
Additional Summary of Pneumonias Infection Rates Up to But Not Including Day 22
Per Protocol Population

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Table 14.2.5.1
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population

Statistics	ASN100 (N=###)	Placebo (N=####)
n	##	##
Mean	##.#	##.#
Standard Deviation	##.##	##.##
Minimum	##	##
Median	##.#	##.#
Maximum	##	##
----- Treatment Comparison (ASN100 vs. Placebo) [1]-----		
P-value	#.####	

[1] P-value is obtained from a Wilcoxon rank sum test.
Total duration (days) of mechanical ventilation is defined as total number of days on mechanical ventilation during the first 21 days post-randomization.

The layout of the following table will be the same as Table 14.2.5.1:

Table 14.2.5.2
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Per Protocol Population

Arsanis, Inc. Program Name: XXXX.sas
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Table 14.2.5.3.1a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Pneumonia (SDO1)

Statistics	ASN100 (N=###)	Placebo (N=####)
n	##	##
Mean	##.#	##.#
Standard Deviation	##.##	##.##
Minimum	##	##
Median	##.#	##.#
Maximum	##	##
----- Treatment Comparison (ASN100 vs. Placebo) [1]-----		
P-value	#.####	

[1] P-value is obtained from a Wilcoxon rank sum test.
Total duration (days) of mechanical ventilation is defined as total number of days on mechanical ventilation during the first 21 days post-randomization.
Note: In subjects who are not confirmed as having pneumonia (SDO1) and who are discontinued from the study due to any cause prior to Day 22, they are considered as not developing pneumonia (SDO1).

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Table 14.2.5.3.1b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Pneumonia (SDO1)

Statistics	ASN100 (N=###)	Placebo (N=####)
n	##	##
Mean	##.#	##.#
Standard Deviation	##.##	##.##
Minimum	##	##
Median	##.#	##.#
Maximum	##	##
----- Treatment Comparison (ASN100 vs. Placebo) [1]-----		
P-value	#.####	

[1] P-value is obtained from a Wilcoxon rank sum test.
Total duration (days) of mechanical ventilation is defined as total number of days on mechanical ventilation during the first 21 days post-randomization.
Note: In subjects who are not confirmed as having pneumonia (SDO1) and who are discontinued from the study due to any cause prior to Day 22, they are considered as developing pneumonia (SDO1).

The layouts of the following tables will be the same as Table 14.2.5.3.1a and 14.2.5.3.1b:

Table 14.2.5.3.2a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Pneumonia (SDO2)

Table 14.2.5.3.2b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Pneumonia (SDO2)

Table 14.2.5.4.1a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with S. aureus Pneumonia (SDO1)

Table 14.2.5.4.1b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with S. aureus Pneumonia (SDO1)

Table 14.2.5.4.2a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with S. aureus Pneumonia (SDO2)

Table 14.2.5.4.2b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with S. aureus Pneumonia (SDO2)

Table 14.2.5.5.1a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Bacterial Pneumonia (SDO1)

Table 14.2.5.5.1b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Bacterial Pneumonia (SDO1)

Table 14.2.5.5.2a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Bacterial Pneumonia (SDO2)

Table 14.2.5.5.2b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Bacterial pneumonia (SDO2)

Table 14.2.5.6.1a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Non-S. aureus Pneumonia (SDO1)

Table 14.2.5.6.1b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Non-S. aureus Pneumonia (SDO1)

Table 14.2.5.6.2a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Non-S. aureus Pneumonia (SDO2)

Table 14.2.5.6.2b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Non-S. aureus Pneumonia (SDO2)

Table 14.2.5.7.1a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Gram Negative Pneumonia (SDO1)

Table 14.2.5.7.1b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Gram Negative Pneumonia (SDO1)

Table 14.2.5.7.2a
Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Gram Negative Pneumonia (SDO2)

Table 14.2.5.7.2b
Additional Analysis of Total Duration (Days) of Mechanical Ventilation During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Gram Negative Pneumonia (SDO2)

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Table 14.2.6.1
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population

Statistics	ASN100 (N=###)	Placebo (N=####)
n	##	##
Mean	##.#	##.#
Standard Deviation	##.##	##.##
Minimum	##	##
Median	##.#	##.#
Maximum	##	##
----- Treatment Comparison (ASN100 vs. Placebo) [1]-----		
P-value	#.####	

[1] P-value is obtained from a Wilcoxon rank sum test.
Total length of ICU stay (days) is defined as the total number of days of ICU stay during the first 21 days post-randomization.

The layout of the following table will be the same as Table 14.2.6.1:

Table 14.2.6.2
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Per Protocol Population

Arsanis, Inc. Program Name: XXXX.sas
Protocol Number: ASN100-201 Run Date: MM/DD/YYYY HH:MM
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Table 14.2.6.3.1a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Pneumonia (SDO1)

Statistics	ASN100 (N=###)	Placebo (N=####)
n	###	###
Mean	##.#	##.#
Standard Deviation	##.##	##.##
Minimum	##	##
Median	##.#	##.#
Maximum	##	##
----- Treatment Comparison (ASN100 vs. Placebo) [1]-----		
P-value	#.####	

[1] P-value is obtained from a Wilcoxon rank sum test.
Total length of ICU stay (days) is defined as the total number of days of ICU stay during the first 21 days post-randomization.
Note: In subjects who are not confirmed as having pneumonia (SDO1) and who are discontinued from the study due to any cause prior to Day 22, they are considered as not developing pneumonia (SDO1).

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Table 14.2.6.3.1b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Pneumonia (SDO1)

Statistics	ASN100 (N=###)	Placebo (N=####)
n	##	##
Mean	##.#	##.#
Standard Deviation	##.##	##.##
Minimum	##	##
Median	##.#	##.#
Maximum	##	##
----- Treatment Comparison (ASN100 vs. Placebo) [1]-----		
P-value	#.####	

[1] P-value is obtained from a Wilcoxon rank sum test.
Total length of ICU stay (days) is defined as the total number of days of ICU stay during the first 21 days post-randomization.
Note: In subjects who are not confirmed as having pneumonia (SDO1) and who are discontinued from the study due to any cause prior to Day 22, they are considered as developing pneumonia (SDO1).

The layouts of the following tables will be the same as Table 14.2.6.3.1a and 14.2.6.3.1b:

Table 14.2.6.3.2a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Pneumonia (SDO2)

Table 14.2.6.3.2b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Pneumonia (SDO2)

Table 14.2.6.4.1a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with S. aureus Pneumonia (SDO1)

Table 14.2.6.4.1b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with S. aureus Pneumonia (SDO1)

Table 14.2.6.4.2a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with S. aureus Pneumonia (SDO2)

Table 14.2.6.4.2b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with S. aureus Pneumonia (SDO2)

Table 14.2.6.5.1a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Bacterial Pneumonia (SDO1)

Table 14.2.6.5.1b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Bacterial Pneumonia (SDO1)

Table 14.2.5.6.2a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Bacterial Pneumonia (SDO2)

Table 14.2.5.6.2b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with All Bacterial pneumonia (SDO2)

Table 14.2.6.6.1a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Non-S. aureus Pneumonia (SDO1)

Table 14.2.6.6.1b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Non-S. aureus Pneumonia (SDO1)

Table 14.2.6.6.2a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Non-S. aureus Pneumonia (SDO2)

Table 14.2.6.6.2b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Non-S. aureus Pneumonia (SDO2)

Table 14.2.6.7.1a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Gram Negative Pneumonia (SDO1)

Table 14.2.6.7.1b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Gram Negative Pneumonia (SDO1)

Table 14.2.6.7.2a
Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Gram Negative Pneumonia (SDO2)

Table 14.2.6.7.2b
Additional Analysis of Total Length of ICU Stay (Days) During First 21 Days Post-Randomization
Modified Intent-to-Treat Population
Subjects with Gram Negative Pneumonia (SDO2)

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Table 14.2.7.1
Analysis of 28-Day All-Cause Mortality Rate
Modified Intent-to-Treat Population

	ASN100 (N=###) n (%)	Placebo (N=###) n (%)
28-Day all-cause mortality rate	### (###.#)	### (###.#)
Subjects censored	### (###.#)	### (###.#)
Kaplan-Meier Estimate (95% CI)	##.# (##.#, ##.#)	##.# (##.#, ##.#)

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

The layouts of the following tables will be the same as Table 14.2.7.1:

Table 14.2.7.2
Analysis of 28-Day All-Cause Mortality Rate
Per Protocol Population

Table 14.2.7.3
Analysis of All-Cause Mortality Rate Through Entire Study Period (Through Day 90)
Modified Intent-to-Treat Population

Table 14.2.7.4
Analysis of All-Cause Mortality Rate Through Entire Study Period (Through Day 90)
Per Protocol Population

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Table 14.2.7.5
Subgroup Analysis: Analysis of 28-Day All-Cause Mortality Rate
Modified Intent-to-Treat Population
By Country

Subgroup	ASN100 (N=###) n/N' (%)	Placebo (N=###) n/N' (%)
Country 1		
28-Day all-cause mortality rate	###/### (###.#)	###/### (###.#)
Subjects censored	###/### (###.#)	###/### (###.#)
Kaplan-Meier Estimate (95% CI)	###/### (###.#)	###/### (###.#)
Country 2		
…		

Percentage is calculated using N' which is the number of subjects in each subgroup as the denominator.

The layout of the following table will be the same as Table 14.2.7.5:

Table 14.2.7.6
Subgroup Analysis: Analysis of All-Cause Mortality Rate Through Entire Study Period (Through Day 90)
Modified Intent-to-Treat Population
By Country

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Table 14.2.8.1
Summary of Proportion of Subjects with Diagnosis of HABP >48 Hours Post-extubation Up to But Not Including Day 22
Modified Intent-to-Treat Population
Extubated Subjects

	ASN100 (N=###) n (%)	Placebo (N=###) n (%)
Subjects with diagnosis of HABP >48 hours Post-extubation up to but not including Day 22	### (###.#)	### (###.#)

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

The layout of the following table will be the same as Table 14.2.8.1:

Table 14.2.8.2
Summary of Proportion of Subjects with Diagnosis of HABP >48 Hours Post-extubation Up to But Not Including Day 22
Per Protocol Population
Extubated Subjects

Arsanis, Inc. Program Name: XXXX.sas
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Table 14.2.9.1
Summary of Proportion of Subjects with Development of VABP Up to But Not Including Day 22
Modified Intent-to-Treat Population

	ASN100 (N=###) n (%)	Placebo (N=###) n (%)
Subjects with development of VABP up to but not including Day 22	### (###.#)	### (###.#)

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

The layout of the following table will be the same as Table 14.2.9.1:

Table 14.2.9.2
Summary of Proportion of Subjects with Development of VABP Up to But Not Including Day 22
Per Protocol Population

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Table 14.3.1.1
Overview of Adverse Events
Safety Population

Category	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Total (N=###) n (%)
Any Adverse Event (AE)	### (###.#)	### (###.#)	### (###.#)
Any Treatment-Emergent Adverse Event (TEAE)	### (###.#)	### (###.#)	### (###.#)
Mild TEAEs	### (###.#)	### (###.#)	### (###.#)
Moderate TEAEs	### (###.#)	### (###.#)	### (###.#)
Severe TEAEs	### (###.#)	### (###.#)	### (###.#)
Drug-Related TEAEs [1]	### (###.#)	### (###.#)	### (###.#)
Serious AEs	### (###.#)	### (###.#)	### (###.#)
Drug-Related Serious AEs	### (###.#)	### (###.#)	### (###.#)
Serious AEs Leading to Death	### (###.#)	### (###.#)	### (###.#)
TEAEs Leading to Discontinuation of Study Drug	### (###.#)	### (###.#)	### (###.#)
Serious TEAEs Leading to Discontinuation of Study Drug	### (###.#)	### (###.#)	### (###.#)

Percentage is calculated using the number of subjects in the column heading as the denominator.
A treatment-emergent adverse events (TEAE) is defined as an AE with a start date and time on or after the initiation of study drug administration. If the time of an AE is missing, it is considered treatment emergent if it starts on the same date as the initiation of study drug administration.
[1] Drug-Related is based on the Investigator's assessment.

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Table 14.3.1.2
Subjects with Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Total (N=###) n (%)
Subjects with any TEAEs	### (###.#)	### (###.#)	### (###.#)
System Organ Class 1	### (###.#)	### (###.#)	### (###.#)
Preferred Term 1	### (###.#)	### (###.#)	### (###.#)
Preferred Term 2	### (###.#)	### (###.#)	### (###.#)
Preferred Term 3	### (###.#)	### (###.#)	### (###.#)
System Organ Class 2	### (###.#)	### (###.#)	### (###.#)
Preferred Term 1	### (###.#)	### (###.#)	### (###.#)
Preferred Term 2	### (###.#)	### (###.#)	### (###.#)
Preferred Term 3	### (###.#)	### (###.#)	### (###.#)

Coding is based on MedDRA Version 19.1.
Percentage is calculated using the number of subjects in the column heading as the denominator.
A treatment-emergent adverse events (TEAE) is defined as an AE with a start date and time on or after the initiation of study drug administration. If the time of an AE is missing, it is considered treatment emergent if it starts on the same date as the initiation of study drug administration.
Subjects with multiple adverse events will be counted only once per system organ class and preferred term.

The layouts of the following tables will be the same as Table 14.3.1.2:

Table 14.3.1.3
Subjects with Treatment-Emergent Serious Adverse Events (TESAEs)
By System Organ Class and Preferred Term
Safety Population

Table 14.3.1.4
Subjects with Drug-Related Treatment-Emergent Adverse Events
By System Organ Class and Preferred Term
Safety Population

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Table 14.3.1.5
Subjects with Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class, Preferred Term and Maximum Severity
Safety Population

System Organ Class Preferred Term Maximum Grade	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Total (N=###) n (%)
Subjects with any TEAEs	### (###.#)	### (###.#)	### (###.#)
Mild	### (###.#)	### (###.#)	### (###.#)
Moderate	### (###.#)	### (###.#)	### (###.#)
Severe	### (###.#)	### (###.#)	### (###.#)
System Organ Class 1	### (###.#)	### (###.#)	### (###.#)
Mild	### (###.#)	### (###.#)	### (###.#)
Moderate	### (###.#)	### (###.#)	### (###.#)
Severe	### (###.#)	### (###.#)	### (###.#)
Preferred Term 1	### (###.#)	### (###.#)	### (###.#)
Mild	### (###.#)	### (###.#)	### (###.#)
Moderate	### (###.#)	### (###.#)	### (###.#)
Severe	### (###.#)	### (###.#)	### (###.#)
Preferred Term 2	### (###.#)	### (###.#)	### (###.#)

Coding is based on MedDRA Version 19.1.
Percentage is calculated using the number of subjects in the column heading as the denominator.
A treatment-emergent adverse events (TEAE) is defined as an AE with a start date and time on or after the initiation of study drug administration. If the time of an AE is missing, it is considered treatment emergent if it starts on the same date as the initiation of study drug administration.
If the same TEAE (based on preferred term) is reported for the same patient more than once, the TEAE is counted only once for that preferred term and at the highest severity.

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Table 14.3.1.6
Subjects with Treatment-Emergent Adverse Events (TEAEs)
By System Organ Class, Preferred Term and Relationship to Study Drug
Safety Population

System Organ Class Preferred Term Strongest Relationship	ASN100 (N=###) n (%)	Placebo (N=###) n (%)	Total (N=###) n (%)
Subjects with any TEAEs	### (###.#)	### (###.#)	### (###.#)
Not Related	### (###.#)	### (###.#)	### (###.#)
Related	### (###.#)	### (###.#)	### (###.#)
System Organ Class 1	### (###.#)	### (###.#)	### (###.#)
Not Related	### (###.#)	### (###.#)	### (###.#)
Related	### (###.#)	### (###.#)	### (###.#)
Preferred Term 1	### (###.#)	### (###.#)	### (###.#)
Not Related	### (###.#)	### (###.#)	### (###.#)
Related	### (###.#)	### (###.#)	### (###.#)
Preferred Term 2	### (###.#)	### (###.#)	### (###.#)

Coding is based on MedDRA Version 19.1.
Percentage is calculated using the number of subjects in the column heading as the denominator.
A treatment-emergent adverse events (TEAE) is defined as an AE with a start date and time on or after the initiation of study drug administration. If the time of an AE is missing, it is considered treatment emergent if it starts on the same date as the initiation of study drug administration.
If the same TEAE (based on preferred term) is reported for the same patient more than once, the TEAE is counted only once for that preferred term and at the strongest relationship to study drug.
Drug-Related is based on the Investigator's assessment.

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Table 14.3.2.1
Listing of Serious Adverse Events
Safety Population

Treatment Subject	VT: Verbatim Term/ PT: Preferred Term/ SOC:System Organ Class	Start Date/Time/Day Stop Date/Time/Day Duration (days)	TEAE?/ Severity	Related to Study Drug	Action Taken/ Other Action Taken/ Outcome
ASN100					
###-###-###	VT: XXXXXXXXXXX/ PT: XXXXXXXXXXXXXXX/ SOC:XXXXXXXXXXXXXXXX	YYYY-MM-DD/HH:MM/## Continuing	Yes/ SEVERE	NOT RELATED	DOSE NOT CHANGED/ MEDICATION REQUIRED/ NOT RECOVERED/NOT RESOLVED
###-###-###	VT: XXXXXXXXXXX/ PT: XXXXXXXXXXXXXXX/ SOC:XXXXXXXXXXXXXXX	YYYY-MM-DD/HH:MM/## YYYY-MM-DD/HH:MM/## ##	Yes/ XXXXXXX	RELATED	XXXXXXXXXX/ XXXXXXXXXX/ XXXXXX
###-###-###	VT: XXXXXXXXXXX/ PT: XXXXXXXXXXXX/ SOC:XXXXXXXXXXXXXXX	YYYY-MM-DD/HH:MM/## YYYY-MM-DD/HH:MM/## ##	Yes/ XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXX/ XXXXXX/ XXXXXXXXX
Placebo					

Coding is based on MedDRA Version 19.1.
Day = Study day and is based on the first dose of study drug which is day 1.
Duration is calculated using stop date of adverse event - start date of adverse event + 1.
A treatment-emergent adverse events (TEAE) is defined as an AE with a start date and time on or after the initiation of study drug administration. If the time of an AE is missing, it is considered treatment emergent if it starts on the same date as the initiation of study drug administration.

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Table 14.3.2.2
Listing of Adverse Events Leading to Discontinuation of Study Drug
Safety Population

Treatment Subject	VT: Verbatim Term/ PT: Preferred Term/ SOC:System Organ Class	Start Date/Time/Day Stop Date/Time/Day Duration (days)	SAE?/ TEAE?/ Severity	Related to Study Drug	Action Taken/ Other Action Taken/ Outcome
ASN100					
###-###-###	VT: XXXXXXXXXX/	YYYY-MM-DD/HH:MM/##	Yes/	NOT RELATED	DOSE NOT CHANGED/
	PT: XXXXXXXXXXXXXX/	Continuing	Yes/		MEDICATION REQUIRED/
	SOC:XXXXXXXXXXXXXXX		SEVERE		NOT RECOVERED/NOT RESOLVED
###-###-###	VT: XXXXXXXXXX/	YYYY-MM-DD/HH:MM/##	Yes/	RELATED	XXXXXXXXX/
	PT: XXXXXXXXXXXXXX/	YYYY-MM-DD/HH:MM/##	Yes/		XXXXXXXXX/
	SOC:XXXXXXXXXXXXXX	##	XXXXX		XXXXXX
###-###-###	VT: XXXXXXXXXX/	YYYY-MM-DD/HH:MM/##	No/	XXXXXXXXX	XXXXXXXXXX/
	PT: XXXXXXXXXXX/	YYYY-MM-DD/HH:MM/##	XXX/		XXXXXX/
	SOC:XXXXXXXXXXXXXX	##	XXXXXX		XXXXXXXXX
Placebo					

Coding is based on MedDRA Version 19.1.
Day = Study day and is based on the first dose of study drug which is day 1.
Duration is calculated using stop date of adverse event - start date of adverse event + 1.
A treatment-emergent adverse events (TEAE) is defined as an AE with a start date and time on or after the initiation of study drug administration. If the time of an AE is missing, it is considered treatment emergent if it starts on the same date as the initiation of study drug administration.

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Table 14.3.3.1
Summary of Laboratory Chemistry Parameters
Safety Population

Parameter (unit) / Visit / Statistics	ASN100 (N=###) Baseline	ASN100 (N=###) Post	ASN100 (N=###) Change	Placebo (N=###) Baseline	Placebo (N=###) Post	Placebo (N=###) Change	Total (N=###) Baseline	Total (N=###) Post	Total (N=###) Change
Parameter 1 (unit)									
Baseline [1]									
n	###			###			###		
Mean	##.##			##.##			##.##		
SD	##.###			##.###			##.###		
Minimum	##.#			##.#			##.#		
Median	##.##			##.##			##.##		
Maximum	##.#			##.#			##.#		
Day 2									
n [2]	###	###	###	###	###	###	###	###	###
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SD	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Day 4									
n [2]	###	###	###	###	###	###	###	###	###
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SD	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#

<< Programming note: Repeat for all scheduled visits. Parameters to be included: Alanine aminotransferase (ALT), Albumin, Alkaline phosphatase, Aspartate aminotransferase (AST), Bicarbonate, Blood urea nitrogen, Calcium, Chloride, Creatinine, Direct bilirubin, Glucose, Phosphorus, Potassium, Sodium, Total bilirubin, and Total protein>>

[1] Baseline is defined as the last measurement or assessment prior to the first and only dose of study drug.
[2] n is the number of subjects with both baseline and post-baseline measurements.

The layouts of the following tables will be the same as Table 14.3.3.1:

Table 14.3.3.2
Summary of Laboratory Hematology Parameters
Safety Population

<<Parameters to be included: Absolute neutrophil count, Hematocrit, Hemoglobin, Platelet count, Red blood cell (RBC) count, White blood cell (WBC) count with differential (basophils, eosinophils, lymphocytes, monocytes, and neutrophils) , RBC indices mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and %Reticulocytes.>>

Table 14.3.3.3
Summary of Laboratory Coagulation Parameters
Safety Population

<< Parameters to be included: Prothrombin time and Partial thromboplastin time (PTT)>>

Table 14.3.3.4
Summary of Laboratory Urinalysis Parameters
Safety Population

<< Parameters to be included: pH and Specific Gravity>>

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Table 14.3.3.5
Shift Table for Hematology Parameters
Safety Population

Parameter (unit) / Treatment	Baseline [1]	Worst Post-baseline Value: Low n (%)	Normal n (%)	High n (%)	Missing n (%)	Total n (%)
Parameter 1 (unit)						
ASN100 (N=###)	Low	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	Normal	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	High	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	Missing	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	Total	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Placebo (N=###)						

<< Programming note: Parameters to be included: Hematocrit, Hemoglobin, Platelets, White blood cell count and differential including Basophils, Neutrophils, Lymphocytes, Monocytes, and Eosinophils>>

[1] Baseline is defined as the last measurement or assessment prior to the first and only dose of study drug.

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Table 14.3.3.6
Shift Table for Chemistry Parameters
Safety Population

Parameter (unit) / Treatment	Baseline [1]	Worst Post-baseline Value: <LLN n (%)	Normal n (%)	>ULN and <=3xULN n (%)	>3xULN and <=5xULN n (%)	>5xULN n (%)	Missing n (%)	Total n (%)
Parameter 1 (unit)								
ASN100 (N=###)	<LLN	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	Normal	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	>ULN and <=3xULN	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	>3xULN and <=5xULN	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	>5xULN	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	Missing	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
	Total	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)	### (###.#)
Placebo (N=###)								

<< Programming note: Parameters to be included: ALT, AST, Total Bilirubin, Creatinine, and ALP>>

[1] Baseline is defined as the last measurement or assessment prior to the first and only dose of study drug.

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Table 14.3.3.7
Number (%) of Subjects with Prespecified Potentially Clinically Significant Abnormal Post-Baseline Liver Function Tests
Safety Population

Parameter Category	ASN100 (N=###) n/N' (%)	Placebo (N=###) n/N' (%)	Total (N=###) n/N' (%)
Subjects with a valid post-baseline value, N'	###	###	###
ALT			
>=3xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
>=5xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
AST			
>=3xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
>=5xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
ALT or AST			
>=3xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
>=5xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)

Percentage is calculated using N', the number of subjects with a valid post-baseline assessment as the denominator.
* Potential Hy's Law case is defined as ALT or AST >=3xULN, Total bilirubin >=2xULN and ALP <= 2xULN.

Table 14.3.3.7
Number (%) of Subjects with Prespecified Potentially Clinically Significant Abnormal Post-Baseline Liver Function Tests
Safety Population

Parameter Category	ASN100 (N=###) n/N' (%)	Placebo (N=###) n/N' (%)	Total (N=###) n/N' (%)
Total bilirubin			
>=1.5xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
>=2xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
ALP			
>=1.5xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
>=3xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
ALT or AST >=3xULN and Total bilirubin >=2xULN	###/### (##.#)	###/### (##.#)	###/### (##.#)
Potential Hy's Law case *	###/### (##.#)	###/### (##.#)	###/### (##.#)

Percentage is calculated using N', the number of subjects with a valid post-baseline assessment as the denominator.
* Potential Hy's Law case is defined as ALT or AST >=3xULN, Total bilirubin >=2xULN and ALP <= 2xULN.

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Table 14.3.3.8
Listing of Subjects with Prespecified Potentially Clinically Significant Abnormal Post-Baseline Liver Function Findings
Safety Population

Treatment Subject	Parameter (Unit)	Normal Range	Visit	Date and Time of Collection/Day	Result	Met Criteria
ASN100						
###-###-###	XXXXXXXX (XXXX)	##.#-##.#	Day 1 Pre-dose	YYYY-MM-DD/HH:MM/##	##.#	
			XXXXXXXXX	YYYY-MM-DD/HH:MM/##	##.#	ALT >= 3xULN
			XXXXXXXXX	YYYY-MM-DD/HH:MM/##	##.#	
			XXXXXXXXX	YYYY-MM-DD/HH:MM/##	##.#	
	XXXXXXXX (XXXX)	##.#-##.#	Day 1 Pre-dose	YYYY-MM-DD/HH:MM/##	##.#	
			XXXXXXXXX	YYYY-MM-DD/HH:MM/##	##.#	AST >= 3xULN
			XXXXXXXXX	YYYY-MM-DD/HH:MM/##	##.#	
			XXXXXXXXX	YYYY-MM-DD/HH:MM/##	##.#	
###-###-###	XXXXXXXX (XXXX)	##.#-##.#	Day 1 Pre-dose	YYYY-MM-DD/HH:MM/##	##.#	
			XXXXXXXXX	YYYY-MM-DD/HH:MM/##	##.#	ALP >= 1.5xULN
			XXXXXXXXX	YYYY-MM-DD/HH:MM/##	##.#	
			XXXXXXXXX	YYYY-MM-DD/HH:MM/##	##.#	
Placebo						

Day = Study day and is based on the first dose of study drug which is day 1.

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Table 14.3.4
Summary of Vital Signs
Safety Population

Parameter (unit) / Visit / Statistics	ASN100 (N=###) Baseline	ASN100 (N=###) Post	ASN100 (N=###) Change	Placebo (N=###) Baseline	Placebo (N=###) Post	Placebo (N=###) Change	Total (N=###) Baseline	Total (N=###) Post	Total (N=###) Change
Parameter 1 (unit)									
Baseline [1]									
n	###			###			###		
Mean	##.##			##.##			##.##		
SD	##.###			##.###			##.###		
Minimum	##.#			##.#			##.#		
Median	##.##			##.##			##.##		
Maximum	##.#			##.#			##.#		
Day 1									
n [2]	###	###	###	###	###	###	###	###	###
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SD	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Day 2									
n [2]	###	###	###	###	###	###	###	###	###
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SD	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#

<< Program note: Repeat for all scheduled visits; Parameters also to be included: Systolic BP (mmHg), Diastolic Blood Pressure (mmHg), Pulse (bpm), Respiratory Rate (rpm), Temperature (C), pH, PaO2 (mmHg), PaCO2 (mmHg), and SpO2 (%)>>

[1] Baseline is defined as the last measurement or assessment prior to the first and only dose of study drug.
[2] n is the number of subjects with both baseline and post-baseline measurements.

Figure Mock-Ups

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Figure 14.2.1.1
Kaplan-Meier Plot of Overall Survival (Days) by Treatment
Modified Intent-to-Treat Population

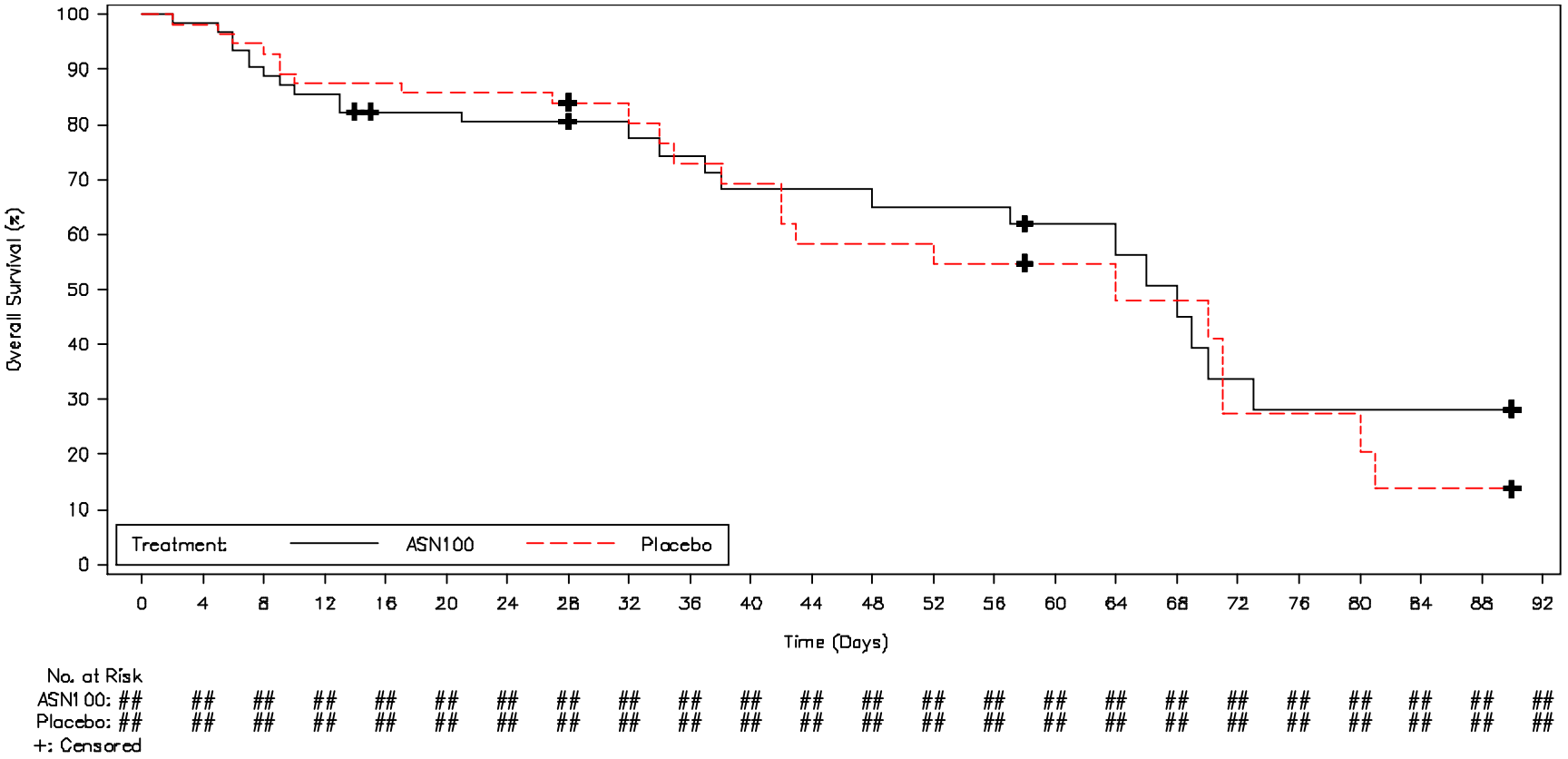

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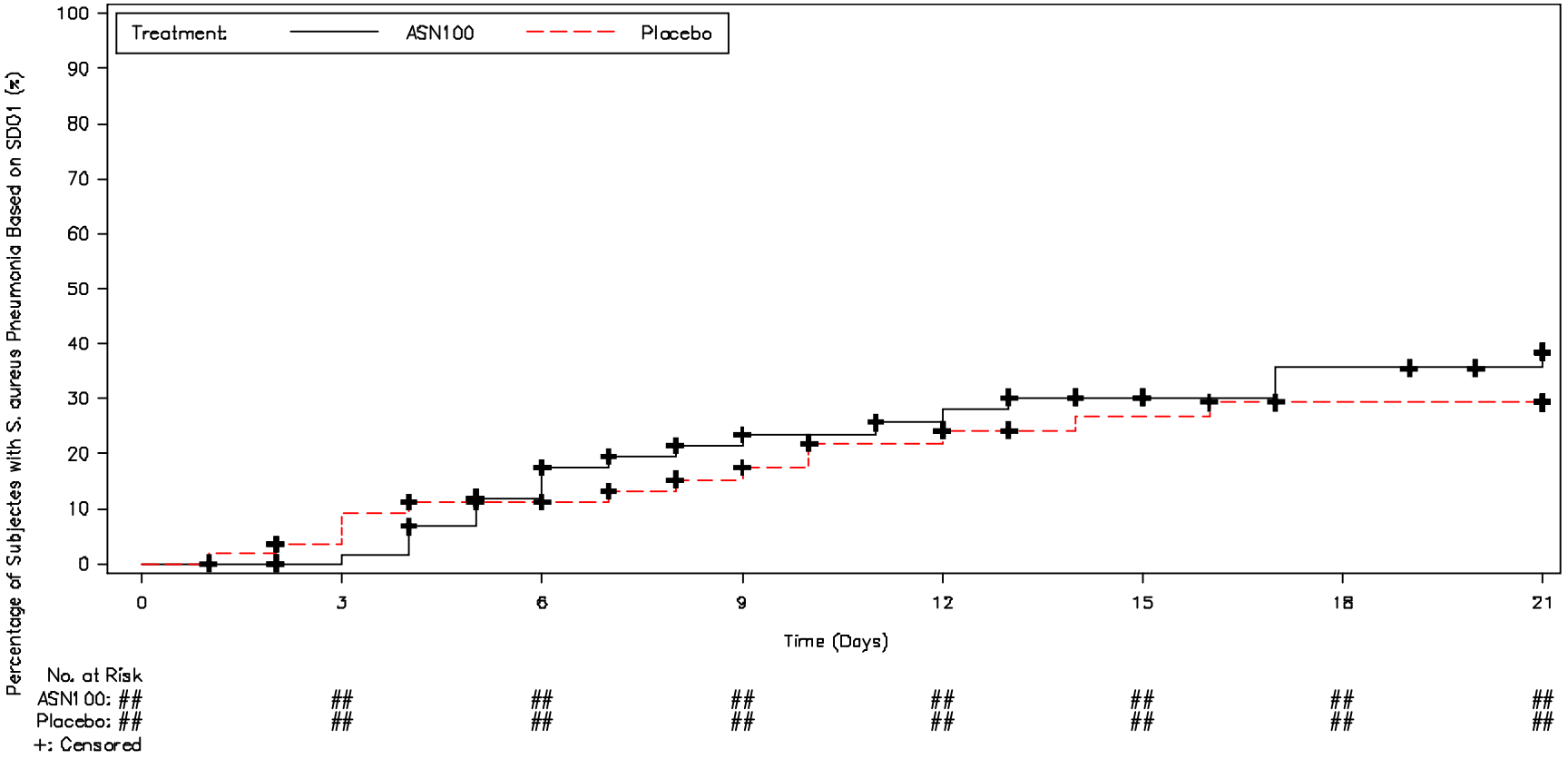
Figure 14.2.2.1
Kaplan-Meier Plot of Time to S. aureus Pneumonias Up to But Not Including Day 22 Based on Sponsor-Defined Outcome (SDO1)
Modified Intent-to-Treat Population



Note: Subjects who did not develop S. aureus pneumonia, discontinued from the study, or died prior to Day 22 will be considered censored.

The layouts of the following tables will be the same as Figure 14.2.2.1:

Figure 14.2.2.2
Kaplan-Meier Plot of Time to S. aureus Pneumonias Up to But Not Including Day 22 Based on Sponsor-Defined Outcome (SDO2)
Modified Intent-to-Treat Population

<< Programming note: For figures 14.2.2.3 and 14.2.2.4, footnote will use "Note: Discontinuation from the study due to any cause up to but not including Day 22 will be considered as an event.">>

Figure 14.2.2.3
Additional Kaplan-Meier Plot of Time to S. aureus Pneumonias Up to But Not Including Day 22 Based on Sponsor-Defined Outcome (SDO1)
Modified Intent-to-Treat Population

Figure 14.2.2.4
Additional Kaplan-Meier Plot of Time to S. aureus Pneumonias Up to But Not Including Day 22 Based on Sponsor-Defined Outcome (SDO2)
Modified Intent-to-Treat Population

<< Programming note: For figure 14.2.2.5, no footnote will be used>>

Figure 14.2.2.5
Kaplan-Meier Plot of Time to S. aureus Pneumonias Up to But Not Including Day 22
Determined by Investigator's Judgement and Review Meeting's Determination of S. aureus as a Causative Pneumonia Pathogen
Modified Intent-to-Treat Population

Listings Mock-ups

Listing 16.2.1.1
Screen Failures
All Subjects

Subject	Date of Screen Failure	Reason for Screen Failure
###-###-###	YYYY-MM-DD	XXXXXXXXXXXXXXXXXXXXXXXX
###-###-###	YYYY-MM-DD	XXXXXXXXXXXXXXXXXXXXXXXX
###-###-###	YYYY-MM-DD	Other: XXXXXXXXXXXXXXXX
###-###-###	YYYY-MM-DD	XXXXXXXXXXX
###-###-###	YYYY-MM-DD	XXXXXXXXXXXXXXXXXXXXXXXX

Note: A subject was considered a screen failure if they were enrolled in the trial and underwent daily screening of endotracheal aspirates for the presence of S. aureus.

Listing 16.2.1.2
Subject Disposition
Intent-to-Treat Population

Treatment Subject	Complete Study?/ Reason Study Not Completed [1]	Date/Study Day of Completion or Early Termination [2]	Prematurely Unblinded?
ASN100			
###-###-###	No/XXXXXXXXXXXXXXX	YYYY-MM-DD/##	No
###-###-###	No/Other:XXXXXXXXX	YYYY-MM-DD/##	Yes
###-###-###	Yes	YYYY-MM-DD/##	No
Placebo			

Day = Study day and is based on first dose of study drug which is Day 1.
[1] Study considered complete if subject completed the study through the Day 90 Safety Visit.
[2] If a subject completed the study, date of completion is displayed. Otherwise, date of early termination is displayed.

Listing 16.2.1.3
Subject Randomization
All Subjects

Treatment / Subject	Protocol Version	Met All Inclusion and No Exclusion Criteria?/ Criteria Not Satisfied	Heavily Colonized with S. aureus?	Remain Mechanically Ventilated?*	Probable Survival?**	Date/Time of Randomization	Kit ID	Receiving Antibiotic? [1]
ASN100								
###-###-###	02May2017	Yes	Yes	Yes	Yes	YYYY-MM-DD/HH:MM	######	Yes
###-###-###	DDMMMYYYY	No/INCL##, EXCL##	Yes	No		YYYY-MM-DD/HH:MM	######	No
Placebo								
Screen Failure								

* In investigator's opinion, subject will require ongoing ventilator support for at least 48 hrs.
** In Investigator's opinion, survival beyond 72 hrs post-randomization is expected.
[1] Is the subject receiving concomitant anti-staphylococcal antibiotics at the time of randomization that are potentially active against S. aureus pneumonia?

Listing 16.2.1.4
Sub-Study for Subjects Diagnosed with Pneumonia
All Subjects

Treatment Subject	Presumed S.aureus Pneumonia at Randomization?	Previous and/or Current Anti-staphylococcal Antibiotic Exposure*
ASN100		
###-###-###	Yes	<24 hours
###-###-###	Yes	>= 24 hours
###-###-###	No	< 72 hours
###-###-###	Yes	>= 72 hours
###-###-###	XXX	############
Placebo		
Screen Failure		

* Previous and/or current anti-staphylococcal antibiotic exposure that is potentially effective against S. aureus pneumonia.

Listing 16.2.2
Protocol Deviations
Intent-to-Treat Population

Treatment / Subject	Occurrence Date/Day	Deviation Type	Protocol Deviation	Action	CSR Reportable?
ASN100					
###-###-###	YYYY-MM-DD/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	Yes
		XXXXXXXX	XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	No
		XXXXXXXX	XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXX
###-###-###	YYYY-MM-DD/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXX
###-###-###	YYYY-MM-DD/##	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXX	XXX
		XXXXXXXX	XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	
###-###-###	YYYY-MM-DD/##	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXX	XXX
Placebo					

Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.3.1
Subject Population
Intent-to-Treat Population

Treatment Subject	ITT Population	MITT Population	Per Protocol Population	Safety Population
ASN100				
###-###-###	Yes	Yes	No	No
###-###-###	Yes	Yes	Yes	Yes
###-###-###	Yes	Yes	Yes	Yes
###-###-###	Yes	Yes	Yes	Yes
###-###-###	Yes	No	Yes	Yes
###-###-###	Yes	Yes	Yes	Yes
Placebo				

Listing 16.2.4.1
Demographics
Intent-to-Treat Population

Treatment / Subject	Date of Informed Consent	Protocol Version	Date of Birth	Age at Enrollment (Years)	Sex	Ethnicity [1]	Race
ASN100							
###-###-###	YYYY-MM-DD	02MAY2017	YYYY-MM	##	F	HT	XXXXXXXX
###-###-###	YYYY-MM-DD	16NOV2016	YYYY-MM	##	M	NHT	Other: XXXXXXXX
###-###-###	YYYY-MM-DD	DDMMMYYYY	YYYY-MM	##	M	NR	XXXXXXXX
###-###-###	YYYY-MM-DD	DDMMMYYYY	YYYY-MM	##	M	UNK	XXXXXXXX
###-###-###	YYYY-MM-DD	DDMMMYYYY	YYYY-MM	##	F	NHT	XXXXXXXX
###-###-###	YYYY-MM-DD	DDMMMYYYY	YYYY-MM	##	M	NHT	XXXXXXXX
Placebo							

[1] Ethnicity: HT = Hispanic or Latino, NHT = Not Hispanic or Latino, NR = Not Reported, UNK = Unknown.

Listing 16.2.4.2
Smoking Medical History
Intent-to-Treat Population

Treatment Subject	History of Smoking?	Packs Smoked Per Week	Duration of Smoking (Years)
ASN100			
###-###-###	Never		
###-###-###	Current	#	##
###-###-###	Former	#	##
Placebo			

Listing 16.2.4.3
Medical History
Intent-to-Treat Population

Treatment / Subject	Event/ Diagnosis	Start Date/Day	End Date/Day
ASN100			
###-###-###	XXXXXXXXXXXX	YYYY-MM-DD/##	YYYY-MM-DD/##
	XXXXXX	YYYY-MM-DD/##	Ongoing
	XXXXXXXXXXXXXXXXXXXX		YYYY-MM-DD/##
###-###-###	XXXXXXXXXXXX	YYYY-MM-DD/##	YYYY-MM-DD/##
Placebo			

Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.4.4
Prior and Concomitant Medications
Intent-to-Treat Population

Treatment Subject	VT: Medication Name PT: Preferred Term ATC:Medication Class	Indication	Dose/ Unit	Frequency/ Route	Start Date/Time/Day/ Stop Date/Time/Day
ASN100					
###-###-###	VT: XXXXXXXXXXXXXXXX PT: XXXXXXXXXXXXXXXX ATC:XXXXXXXXXXXXXXXX	XXXXXXXXX	YXXXXXXXXXX/ YXXXXXXXX	XXXXXXXXX/ XXXXXXXXX	YYYY-MM-DD/HH:MM/##/ YYYY-MM-DD/HH:MM/##
###-###-###	VT: XXXXXXXXXXXXXXXX PT: XXXXXXXXXXXXXXXX ATC:XXXXXXXXXXXXXXXX	XXXXXXX	XXXXXXXXXX/ Other: XXXXX	Other: XXX/ Other: XXXX	YYYY-MM-DD/HH:MM/## Ongoing
Placebo					

Coding is based on WHO Drug Dictionary Sept 2016E B2.
Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.4.5
Concomitant Procedure and Non-Drug Therapies
Intent-to-Treat Population

Treatment / Subject	VT: Procedure/Non-Drug Therapy PT: Preferred Term SOC:System Organ Class	Indication	Start Date/Time/Day Stop Date/Time/Day
ASN100			
###-###-###	VT: XXXXXXXXXXXXXXXXXXXXXXXXX PT: XXXXXXXXXXXXXXXXXXXXXXXXX SOC:XXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXX	YYYY-MM-DD/HH:MM/## YYYY-MM-DD/HH:MM/##
	VT: XXXXXXXXXXXXXXXXXXXXXXXXX PT: XXXXXXXXXXXXXXXXXXXXXXXXX SOC:XXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXX	YYYY-MM-DD/HH:MM/## YYYY-MM-DD/HH:MM/##
###-###-###	VT: XXXXXXXXXXXXXXXXXXXXXXXXX PT: XXXXXXXXXXXXXXXXXXXXXXXXX SOC:XXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXX	YYYY-MM-DD/HH:MM/## Ongoing
Placebo			

Coding is based on MedDRA Version 19.1.
Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.4.6
Ventilator Status
Intent-to-Treat Population

Treatment Subject	Underlying Condition [1]	Start Date/Time of Initial Intubation	Visit	Mechanically Ventilated at This Visit?	Type [2]	FiO2* (%)	PEEP** (cm H2O)	Is Subject Currently Extubated or Since Previous Assessment?	Date/Time of Extubation
ASN100									
###-###-###	T, CI, NI	YYYY-MM-DD/HH:MM	XXXXX	Yes	E	##	#####	Yes	YYYY-MM-DD/HH:MM
			XXXXX	No				Yes	YYYY-MM-DD/HH:MM
			XXXXX	Yes	T	##	#####	No	
###-###-###	Other: XXXXX	YYYY-MM-DD/HH:MM	XXXXX	Yes	OTH	##	#####	Yes	YYYY-MM-DD/HH:MM
			XXXXX	No				Yes	YYYY-MM-DD/HH:MM
			XXXXX	Yes	E	##	#####	No	
Placebo									

[1] T = Trauma, CI = Cardiovascular Impairment, NI = Neurological Impairment, PI = Pulmonary Impairment, Other.
[2] E = Endotracheal, T = Tracheotomy, OTH = Other.
* Predominant FiO2 setting (%) in the past 24 hours.
** Predominant PEEP setting (cm H2O) in the past 24 hours.

Listing 16.2.4.7
Risk Factors for Ventilator - Associated Pneumonia
Intent-to-Treat Population

Treatment Subject	Risk Factors	Intubated Previously?	Is Subject Receiving Enteral Tube Feeding?
ASN100			
###-###-###	COPD, Coma, ARDS	Unknown	Yes
###-###-###	None	Yes	No
###-###-###	ARDS, ICP monitor	Yes	Yes
###-###-###	COPD	No	Yes
Placebo			

Listing 16.2.4.8
VAP Prevention
Intent-to-Treat Population

Treatment Subject	Visit	VAP Prevention?	Techniques Applied	Silver Impregnated Endotracheal Tube Used?
ASN100				
###-###-###	XXXXXX	Yes	Elevation of head of the bed; Daily sedation vacations and assessment of readiness to extubate; Peptic ulcer disease prophylaxis; Deep vein thrombosis prophylaxis; Daily oral care with chlorhexidine or equivalent;	No
###-###-###	XXXXXX	No		Unknown
###-###-###	XXXXXX	Yes	Elevation of head of the bed; Peptic ulcer disease prophylaxis;	Yes
###-###-###	XXXXXX	No		Yes
Placebo				

Listing 16.2.5.1
Study Drug Administration
Intent-to-Treat Population

Treatment Subject	Date/Time/Day of Drug Preparation	Bag	----- Infusion ---- Start Date/Time/Day/ End Date/Time/Day	Total Volume Infused (mL)/ Entire Bag Infused?	Line Flushed?/ Reason Not Done	True Stop Time of Flush Known?/ Est. Stop Time of Flush Aval.?*/ Stop Time
ASN100						
###-###-###	YYYY-MM-DD/HH:MM/##	A	YYYY-MM-DD/HH:MM/##/ YYYY-MM-DD/HH:MM/##	######/ Yes	Yes	Yes/-/HH:MM
		B	YYYY-MM-DD/HH:MM/##/ YYYY-MM-DD/HH:MM/##	######/ No	No/XXXXXXX	
###-###-###	YYYY-MM-DD/HH:MM/##	A	YYYY-MM-DD/HH:MM/##/ YYYY-MM-DD/HH:MM/##	######/ Yes	Yes	No/Yes/HH:MM
		B	YYYY-MM-DD/HH:MM/##/ YYYY-MM-DD/HH:MM/##	######/ Yes	Yes	No/No/
Placebo						

Day = Study day and is based on first dose of study drug which is Day 1.
* Only collected if line was flushed and if the true stop time of flush not known.

Listing 16.2.5.2
Pharmacokinetic Serum Sampling
Intent-to-Treat Population

Treatment Subject	Visit	Time Point	Date/Time/Day of Collection/ Not performed - Reason Not Done
ASN100			
###-###-###	Day 1	+15 min	YYYY-MM-DD/HH:MM/##
		6 hrs	Site Error
		24 hrs	Other: XXXXXXXX
	Day 2	+/- 1 hr relative to BAL fluid collection	YYYY-MM-DD/HH:MM/##
	Day 3	+/- 1 hr relative to BAL fluid collection	YYYY-MM-DD/HH:MM/##
	Day 4		YYYY-MM-DD/HH:MM/##
	Day 7		YYYY-MM-DD/HH:MM/##
	Day 14		YYYY-MM-DD/HH:MM/##
	Day 22		YYYY-MM-DD/HH:MM/##
Placebo			

Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.5.3
Pharmacokinetic BAL Sampling
Intent-to-Treat Population

Treatment Subject	Visit	Collected?/ Reason Not Done	Collection Date/Time/Day
ASN100			
###-###-###	Day 2	Yes	YYYY-MM-DD/HH:MM/##
	Day 3	No/Other: XXXXXXXXX	
Placebo			

Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.6.1
ETA Specimen Culture
Intent-to-Treat Population

Treatment Subject	Visit	ETA Collected?/ Reason Not Done	Date/Time/Day of Collection	Identified?/ Number of Unique Organisms	Genus and Species	MRSA or MSSA? [1]	Result	Isolate Stored for Shipment?/ Local Lab ID
ASN100								
###-###-###	XXXXXX	Yes	YYYY-MM-DD/HH:MM/##	Yes/3	Staphylococcus aureus	MRSA	1+	Yes/###
					XXXXXXXXXXXXXXXXX		>10^5	No
					Other: XXXXXXXXXX		3+	No
###-###-###	XXXXXX	Yes	YYYY-MM-DD/HH:MM/##	No				
###-###-###	XXXXXX	No/Other: XXXXXXX						
Placebo								

Day = Study day and is based on first dose of study drug which is Day 1.
[1] MRSA or MSSA: MRSA, MSSA, or ND = Not Determined. Collected only if Staphylococcus aureus specified.

Listing 16.2.6.2
Respiratory Culture from Local Laboratory
Intent-to-Treat Population

Treatment Subject	Visit	Date/Time/Day Sample Collected or Reason Not Done	Type[1]/ Squ.[2]/ PMNs[3]	Pathogen Isolated?/ Number of Unique Pathogens	Semi-quantitative or Quantitative?/ Specify Pathogen	MRSA or MSSA? [4]	Result	Stored for Shipment?/ Local Lab ID
ASN100								
###-###-###	XXXXXX	YYYY-MM-DD/HH:MM/ ##	XXXX/ Yes/ No	Yes/3	Quantitative/ Staphyloccus aureus	MRSA	>##x10^6	Yes/###
					Semi-quantitative/ Escherichia coli		#+	Yes/####
					XXXXXXX/ Other:XXXXXXXXXXXX		##	No
	XXXXXXX	YYYY-MM-DD/HH:MM/ ##	Oth:XXXXX XXXXXXX/ Yes/ Yes	No				
###-###-###	XXXXXXX	No/Subject Refused						
	XXXXXXX	No/Other: XXXXXXX						
Placebo								

Day = Study day and is based on first dose of study drug which is Day 1.
[1] NBB = Non-Bronchoscopic BAL, PBS = Protected brush specimen, ES = Expectoracted or induced sputum, Oth = Other.
[2] Did the specimen contain <10 squamous epithelial cells/100 x field? Collected if type is expectorated or induced sputum.
[3] Did the specimen contain >25 PMNs/100 x field? Collected if type is expectorated or induced sputum.
[4] MRSA or MSSA: MRSA, MSSA, or ND = Not Determined. Collected ony if Staphylococcus aureus specified.

Listing 16.2.6.3
Blood Culture from Local Laboratory
Intent-to-Treat Population

Treatment Subject	Visit	Collected?/ Reason Not Done	Date/Time/Day of Collection	Pathogen Isolated?/ Number of Unique	Genus and Species	MRSA or MSSA? [1]	Stored for Shipment?/ Local Lab ID
ASN100							
###-###-###	XXXXXX	Yes	YYYY-MM-DD/HH:MM/##	Yes/2	Staphylococcus aureus Other: XXXXXXXXXXXXXXXXXX Enterococcus faecium	MRSA	No
	XXXXXXX	Yes	YYYY-MM-DD/HH:MM/##	Yes/1	XXXXXXXXXXXXXXXXXXXXXXXX		
###-###-###	XXXXXXX	No/Other: XXXXX					
Placebo							

Day = Study day and is based on first dose of study drug which is Day 1.
[1] MRSA or MSSA: MRSA, MSSA, or ND = Not Determined. Collected ony if Staphylococcus aureus specified.

Listing 16.2.6.4
Other Cultures from Local Laboratory
Intent-to-Treat Population

Treatment / Subject	Visit	Other Specimen Collected?/ Reason Not Done	S. aureus Isolated?	Source	Date/Time/Day of Collection	Number of Unique S. aureus	MRSA or MSSA? [1]	Isolate Stored for Shipment to Central Lab	Local Lab ID
ASN100									
###-###-###	XXXXXX	Yes	Yes	Urine	YYYY-MM-DD/HH:MM/##	2	MRSA	Yes	####
				XXXXXX	YYYY-MM-DD/HH:MM/##	0		No	
				Other:XXXX	YYYY-MM-DD/HH:MM/##	1	MRSA	Yes	####
	XXXXXXX	Yes	No						
###-###-###	XXXXXXx	No/Other: XXX							
Placebo									

Day = Study day and is based on first dose of study drug which is Day 1.
[1] MRSA or MSSA: MRSA, MSSA, or ND = Not Determined.

Listing 16.2.6.5
Nasal Swab Specimen
Intent-to-Treat Population

Treatment / Subject	Swab Collected from Right Nostril?	Date/Time/Day of Right Nostril Collection	Swab Collected from Left Nostril?	Date/Time/Day of Left Nostril Collection	Reason Not Collected*
ASN100					
###-###-###	Yes	YYYY-MM-DD/HH:MM/##	No		XXXXXXXXXXXXXXX
###-###-###	Yes	YYYY-MM-DD/HH:MM/##	Yes	YYYY-MM-DD/HH:MM/##	
###-###-###	Yes	YYYY-MM-DD/HH:MM/##	Yes	YYYY-MM-DD/HH:MM/##	
###-###-###	No		No		XXXXXXXXXXXXXXX
Placebo					

Day = Study day and is based on first dose of study drug which is Day 1.
* Applies to swab collection from either right or left nostril.

Listing 16.2.6.6
Microbiological Results from Central Laboratory
Intent-to-Treat Population

Treatment / Subject	Visit	Specimen Collection Date/Time/Day	Source of Specimen	Local Specimen Number	Central Genus and Species	Inducible Clindamycin Resistance	Antimicrobial	MIC(ug/mL) Result	MIC(ug/mL) Interp.
ASN100									
###-###-###	XXXXXX	YYYY-MM-DD/HH:MM/##	ETA	####	Staphylococcus aureus	Negative	Ampicillin	0.120	S
							Ceftaroline	20.000	I
							XXXXXXXXXX	##.###	R
							XXXXXXXXXX	<#####	NA
	XXXXXX	YYYY-MM-DD/HH:MM/##	Respiratory	####	Klebsiella pneumoniae	Positive	XXXXXXXXXX	##.###	I
							XXXXXXXXXX	##.###	I
							XXXXXXXXXX	##.###	R
							XXXXXXXXXX	##.###	I
			NASAL SWAB	####	Staphylococcus aureus	Negative	XXXXXXXXXX	##.###	I
							XXXXXXXXXX	##.###	I
							XXXXXXXXXX	##.###	NA
							XXXXXXXXXX	##.###	I
Placebo									

Day = Study day and is based on first dose of study drug which is Day 1.
MIC Interpretation: S = Susceptible, I = Intermediate, R = Resistant, NA = Not Available.

Listing 16.2.6.7
Radiograph and Imaging
Intent-to-Treat Population

Treatment Subject	Visit	Imaging Preformed?/ Reason Not Done	Type	Date/Time/Day Performed	Infiltrates Present?/ Consistent with Pneumonia?	Description of Infiltrates
ASN100						
###-###-###	XXXXX	Yes	XXXXXXX	YYYY-MM-DD/HH:MM/##	Yes/Yes	Other: XXXXXXX
	XXXXX	Yes	Other: XXXXXXXX	YYYY-MM-DD/HH:MM/##	No	
	XXXXX	No/Other: XXXXX				
###-###-###	XXXXX	No/XXXXXXXXXXXXX				
	XXXXX	Yes	XXXXXXXXX	YYYY-MM-DD/HH:MM/##	Yes/No	XXXXXXXXXXXXXXX
Placebo						

Day = Study day and is based on first dose of study drug day which is Day 1.

Listing 16.2.6.8
Clinical Signs and Symptoms - Pneumonia
Intent-to-Treat Population

Treatment / Subject	Visit	Item	Result
ASN100			
###-###-###	XXXXXX	Was a chest assessment performed?/Reason if not assessed	Yes
		Date/Time/Day performed	YYYY-MM-DD/HH:MM/##
		Does chest x-ray show new or progressive infiltrates suggestive of pneumonia?	No
		Has the subject been hospitalized for > 48 hours?	Yes
		Has the subject received mechanical ventilation via an endotracheal or nasotracheal tube for >= 48 hours?	Yes
		Has the subject developed clinical signs and symptoms within 7 days following hospital discharge?	No
		Has the subject developed new onset or worsening pulmonary signs or symptoms or the requirement for mechanical ventilation?	No
		Was there a need for acute changes in ventilator support to enhance oxygenation or to the amount of PEEP?	No
		Was there new onset of suctioned respiratory secretions?	No
		Was temperature > 38°C or < 35°C? No	
		Was WBC count >= 10,000 cell/mm3 or <= 4500 cell/mm3?	No
		Was > 15% immature neutrophils (bands) seen on peripheral blood smear?	No
		Was diagnosis of pneumonia made?	No
		Was an antibiotic started for treatment of pneumonia?	No
		Concomitant antibiotic medication #	N/A
	XXXXXX	Was a chest assessment performed?/Reason if not assessed	Yes
		Date/Time/Day performed	YYYY-MM-DD/HH:MM/##
		Does chest x-ray show new or progressive infiltrates suggestive of pneumonia?	No
		Has the subject been hospitalized for > 48 hours?	Yes
		Has the subject received mechanical ventilation via an endotracheal or nasotracheal tube for >= 48 hours?	Yes
		…	
Placebo			

Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.6.9
Clinical Signs and Symptoms and Pneumonia Progression
Pilot Rx Arm Amendment
Intent-to-Treat Population

Treatment Subject	Visit	Date/Time/Day of Assessment/ Reason Not Done	Cough?/Rales?/ Percussion Dullness?	Bronchial Sounds?/ Egophony?	Suctioning?/ Ventilator?	Fever (>=38 C)	Purulent Secretions	Dyspnea?/ Tachypnea	Hypoxemia?/ Supplemental O2
ASN100									
###-###-###	XXXXXX	YYYY-MM-DD/HH:MM/ ##	Yes/Yes/ Yes	Yes/ No	Yes/ Yes	Yes	No	Yes/ No	Yes/ Yes
	XXXXXX	YYYY-MM-DD/HH:MM/ ##	Yes/Yes/ Yes	Yes/ No	Yes/ Yes	Yes	No	Yes/ No	Yes/ Yes
	XXXXXX	No/XXXXXXXXXX							
Placebo									

Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.6.10
Investigator Clinical Outcome of Pneumonia
Pilot Rx Arm Amendment
Intent-to-Treat Population

Treatment / Subject	Visit	Date/Time/Day of Assessment/ Reason Not Done	Pneumonia Status	Continued Antibiotic Therapy Required?	Antibiotic Therapy Changed?*
ASN100					
###-###-###	XXXXXX	YYYY-MM-DD/HH:MM/##	Continues	Yes	
	XXXXXX	YYYY-MM-DD/HH:MM/##	Continues	Yes	
	Day 3	YYYY-MM-DD/HH:MM/##	Continues	Yes	Yes
	XXXXXX	YYYY-MM-DD/HH:MM/##	Resolved	No	
	XXXXXX	YYYY-MM-DD/HH:MM/##			
###-###-###	XXXXXX	YYYY-MM-DD/HH:MM/##	Continues	Yes	
	XXXXXX	YYYY-MM-DD/HH:MM/##	XXXXXXXXXXXXXX		
Placebo					

Day = Study day and is based on first dose of study drug which is Day 1.
* Was antibiotic therapy changed within the first 48 hours based on insufficient therapeutic effect?

Listing 16.2.6.11
Hospitalization Course and Discharge
Intent-to-Treat Population

Treatment Subject	Date/Time/Day of Admission	Type of Admission	ICU Specify [1]	Discharged?	Date/Time/Day of Discharge	Type of Discharge
ASN100						
###-###-###	YYYY-MM-DD/HH:MM/##	ICU	XXXXXXX	Yes	YYYY-MM-DD/HH:MM/##	XXXXXXXXXXXXXXXXXXXXX
	YYYY-MM-DD/HH:MM/##	Non-ICU		No		
###-###-###	YYYY-MM-DD/HH:MM/##	ICU	Other: XXX	Yes	YYYY-MM-DD/HH:MM/##	Other: XXXXXXXXXXXXXX
Placebo						

Day = Study day and is based on first dose of study drug which is Day 1.
[1] MIC = Medical ICU, SICU = Surgical ICU, TICU = Trauma ICU, NICU = Neuro ICU, CCU = Coronary Care Unit, Other.

Listing 16.2.6.12
Anti-Drug Antibodies Sample Collection
Intent-to-Treat Population

Treatment Subject	Visit	Collected?	Reason Sample Not Collected
ASN100			
###-###-###	Day 1	Yes	
	Day 22	No	Other: XXXXXX
	Day 90	Yes	
###-###-###	XXXXX	No	XXXXXXXXXXXXXXX
Placebo			

Listing 16.2.6.13
Survival Status
Intent-to-Treat Population

Treatment Subject	Visit	Date of Visit/Day	Survival Status	Date of Death/Day	Reason for Status Unknown
ASN100					
###-###-###	Day ##	YYYY-MM-DD/##	Alive		
###-###-###	Day ##	YYYY-MM-DD/##	Alive		
###-###-###	Day ##		Dead	YYYY-MM-DD/##	
###-###-###	Day ##		Unknown		XXXXXXXXXXXXXXXXXXXXX
Placebo					

Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.7.1
Adverse Events
Intent-to-Treat Population

Treatment / Subject	VT: Verbatim Term / PT: Preferred Term / SOC:System Organ Class	Start Date/Time/Day / Stop Date/Time/Day / Duration (days)	SAE?/ TEAE?/ Severity	Related to Study Drug	Action Taken/ Other Action Taken/ Outcome
ASN100					
###-###-###	VT: XXXXXXXXXXXXXXXXXXXXXXXX	YYYY-MM-DD/HH:MM/##/	No/	NOT RELATED	XXXXXX/
	PT: XXXXXXXXXXXXXXXXXXXXXXXX	YYYY-MM-DD/HH:MM/##/	Yes/		XXXXXXXX/
	SOC:XXXXXXXXXXXXXXXXXXXXXXXX	##	SEVERE		FATAL
###-###-###	VT: XXXXXXXXXXXXXXXXXXXXXXXX	YYYY-MM-DD/HH:MM/##/	No/	RELATED	XXXXXXXX/
	PT: XXXXXXXXXXXXXXXXXXXXXXXX		No/		XX /
	SOC:XXXXXXXXXXXXXXXXXXXXXXXX		MILD		NOT RECOVERED/NOT RESOLVED
	VT: XXXXXXXXXXXXXXXXXXXXXXXX	YYYY-MM-DD/HH:MM/##/	No/	NOT RELATED	XXXXXXXXX/
	PT: XXXXXXXXXXXXXXXXXXXXXXXX	YYYY-MM-DD/HH:MM/##/	Yes/		XXX
	SOC:XXXXXXXXXXXXXXXXXXXXXXXX	##	MODERATE		RECOVERED/RESOLVED WITH SEQUALE
Placebo					

Coding is based on MedDRA Version 19.1.
Day = Study day and is based on the first dose of study drug which is day 1.
Duration is calculated using stop date of adverse event - start date of adverse event + 1.
A treatment-emergent adverse event (TEAE) is defined as an AE with a start date and time on or after the initiation of study drug administration. If the start time of an AE is missing, it is considered treatment emergent if it starts on the same date as the initiation
of study drug administration.

Listing 16.2.7.2
Serious Adverse Events
Intent-to-Treat Population

Treatment Subject	AE Num	VT: Verbatim Term PT: Preferred Term SOC:System Organ Class	Birth Defect/ Significant Disability	Death/ Autopsy/ Date/Day of Death	Hospitalization/ Life Threatening/ Other Medically Important Event	Other Possible Causes	Event Description
ASN100							
###-###-###	#	VT: XXXXXXXXXXXXXXXXXXXX PT: XXXXXXXXXXXXXXXXXXXX SOC:XXXXXXXXXXXXXXXXXXXX	No/ No	No/ No/ YYYY-MM-DD/##	No Yes/ Yes	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXX	#	VT: XXXXXXXXXXXXXXXXXXXX PT: XXXXXXXXXXXXXXXXXXXX SOC:XXXXXXXXXXXXXXXXXXXX	No/ No	No	Yes/ No/ Yes	XXXXXXXXXXXXXX	
Placebo							

Coding is based on MedDRA Version 19.1.
Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.8.1
Central Laboratory Parameters - Chemistry
Intent-to-Treat Population

Treatment Subject	Parameter (Unit)	Normal Range	Visit	Date/Time/Day Collection	Result	Reference Range [1]	Comments
ASN100							
###-###-###	XXXXXXX (XX)	## - ###	XXXXX	YYYY-MM-DD/HH:MM/##	###	LN	
			XXXXX	YYYY-MM-DD/HH:MM/##	###	LN	
			XXXXX	YYYY-MM-DD/HH:MM/##	###	N	
	XXXXXXX (XX)	## - ###	XXXXX	YYYY-MM-DD/HH:MM/##	###	N	
			XXXXX	YYYY-MM-DD/HH:MM/##	###	N	
			XXXXX	YYYY-MM-DD/HH:MM/##	###		
###-###-###							
Placebo							

Day = Study day and is based on first dose of study drug which is Day 1.
[1] LN = Low Normal, LP = Low Panic, N = Normal, HN = High Normal, HP = High Panic, AB = Abnormal, SC = See Comment.

The layouts of the following listings will be the same as listing 16.2.8.1:

Listing 16.2.8.2
Central Laboratory Parameters – Hematology
Intent-to-Treat Population

Listing 16.2.8.3
Central Laboratory Parameters – Urinalysis
Intent-to-Treat Population

Listing 16.2.8.4
Central Laboratory Parameters – Coagulation
Intent-to-Treat Population

Listing 16.2.8.5
Central Laboratory Parameters – Procalcitonin
Intent-to-Treat Population

Listing 16.2.8.6
Urine Pregnancy Test from Local Laboratory
Intent-to-Treat Population

Treatment Subject	Visit	Date/Time/Day of Urine Sample/ Reason Not Done	Result
ASN100			
###-###-###	XXXXX	Other: XXXXXXXXXXXXXXXXXXX	
###-###-###	XXXXX	YYYY-MM-DD/HH:MM/##	Negative
###-###-###	XXXXX	YYYY-MM-DD/HH:MM/##	Negative
###-###-###	XXXXX	Female not of childbearing potential	
Placebo			

Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.8.7
Vital Signs
Intent-to-Treat Population

Treatment Patient	Visit	Date/Time/Day of Collection/ Reason Not Done	Height (cm)	Weight (kg)	SBP (mmHg)	DBP (mmHg)	Pulse (bpm)	Respiratory Rate (breaths/min)	Temp (C)/ Time	pH	PaO2 (mmHg)	PaCO2 (mmHg)	SpO2 (%)
ASN100													
###-###-###	SCR	YYYY-MM-DD/HH:MM/##	##	##	###	###	##	###	##/HH:MM	##	###	###	##
	XXXXX	YYYY-MM-DD/HH:MM/##			###	###	##	###	##/HH:MM				##
	XXXXX	YYYY-MM-DD/HH:MM/##			###	###	##	###	##/HH:MM	##	###	###	
	XXXXX	YYYY-MM-DD/HH:MM/##			###	###	##	###	##/HH:MM	##	###	###	
###-###-###	SCR	Site Error											
	XXXXX	Other: XXXXXXXXXXXX											
	XXXXX	YYYY-MM-DD/HH:MM/##			###	###	##	###	##/HH:MM	##	###	###	##
Placebo													

Day = Study day and is based on first dose of study drug which is Day 1.

Listing 16.2.8.8
12-Lead Electrocardiogram
Intent-to-Treat Population

Treatment / Subject	Visit	Date/Time/Day of Measurement/ Reason Not Done	HR	PR	QRS	QT	RR	Overall Interpretation	Clinically Significant?
ASN100									
###-###-###	Screening	YYYY-MM-DD/HH:MM/##	###	###	###	###	###	Abnormal	No
	Day 1	YYYY-MM-DD/HH:MM/##	###	###	###	###	###	Normal	
	Day ##	Other: XXXX							
	Day ##	Subject Refused							
###-###-###	Screening	Site Error							
	Day 1	YYYY-MM-DD/HH:MM/##	###	###	###	###	###	Normal	
	Day ##	YYYY-MM-DD/HH:MM/##	###	###	###	###	###	Normal	
	Day ##	YYYY-MM-DD/HH:MM/##	###	###	###	###	###	Not Evaluable	
Placebo									

Day = Study day and is based on first dose of study drug which is Day 1.
Note: Unit of HR is bpm, and units of other measurements are msec.

Listing 16.2.8.9
Physical Examination
Intent-to-Treat Population

Treatment / Subject	Visit	Date/Time/Day Performed/ Reason Not Done	Overall Assessment*	Specify Abnormalities
ASN100				
###-###-###	Screening	YYYY-MM-DD/HH:MM/##	Normal	
	Day 1	YYYY-MM-DD/HH:MM/##	Abnormal and CS	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	Day ##	YYYY-MM-DD/HH:MM/##	Abnormal but NCS	
	XXXXXX	Other: XXXXXXX		
###-###-###	Screening	Site Error		
	Day 1	YYYY-MM-DD/HH:MM/##	Abnormal and CS	XXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXX	Subject Refused		
Placebo				

Day = Study day and is based on first dose of study drug which is Day 1.
* CS = Clinically Significant, NCS = Not Clinically Significant.