Trial Summary Report

Date: 05/31/2023
Record Verification Date: 03/17/2023

Trial Identification	
Trial Category	Complete
Trial Type	Interventional
NCI Trial Identifier	NCI-2019-07902
Other Trial Identifiers	
Lead Organization Identifier	ADVL18P1
ClinicalTrials.gov Identifier	NCT04203316
DCP Identifier	No Data Available
CTEP Identifier	ADVL18P1
CCR Identifier	No Data Available
Amendment Number	4
Amendment Date	12/15/2022

General Trial Details	
Type	Interventional
Official Title	An Open-Label Feasibility Study to Assess the Safety and Pharmacokinetics of Enasidenib in Pediatric Patients with Relapsed/Refractory Acute Myeloid Leukemia (R/R-AML) with an Isocitrate Dehydrogenase-2 (IDH2) Mutation
Brief Title	Enasidenib for the Treatment of Relapsed or Refractory Acute Myeloid Leukemia Patients with an IDH2 Mutation
Acronym	No Data Available
Brief Summary	
This trial studies the side effects of enasidenib and to see how well it works in treating patients with acute myeloid leukemia that has come back after treatment (relapsed) or has been difficult to treat with chemotherapy (refractory). Patients must also have a specific genetic change, also called a mutation, in a protein called IDH2. Enasidenib may stop the growth of cancer cells by blocking the mutated IDH2 protein, which is needed for cell growth.	
Detailed Description	
PRIMARY OBJECTIVES: I. To determine the safety of treatment with enasidenib mesylate (enasidenib) administered at continuous daily oral dosing for a 28-day cycle up to 12 cycles in pediatric patients with IDH2-mutant relapsed/refractory (R/R)-acute myeloid leukemia (AML). II. To characterize the plasma pharmacokinetic (PK) profile of enasidenib in pediatric patients with IDH2-mutant R/R-AML. SECONDARY OBJECTIVES: I. To investigate the pharmacodynamic (PD) relationship of oncogenic metabolite	

2-hydroxyglutarate (2-HG) to enasidenib treatment in pediatric patients with IDH2-mutant R/R-AML.
II. To describe the clinical activity of enasidenib in pediatric patients with IDH2-mutant R/R-AML.

OUTLINE:
Patients receive enasidenib orally (PO) once daily (QD) on days 1-28. Treatment repeats every 28 days for up to 12 cycles in the absence of disease progression or unacceptable toxicity. Patients also undergo bone marrow aspiration and/or biopsy and collection of blood on study.

After completion of study treatment, patients are followed up at 30 days, then periodically up to 1 year.

Sponsor	Children's Oncology Group
Lead Organization	Children's Oncology Group
Principal Investigator	Zarnegar-Lumley, Sara
Responsible Party	Sponsor
Overall Official	Zarnegar-Lumley, Sara (Principal Investigator), Children's Oncology Group

Status/Dates

Current Trial Status	Active as of 01/30/2023
Trial Start Date	03/30/2020-Actual
Primary Completion Date	12/31/2030-Anticipated
Trial Completion Date	12/31/2030-Anticipated

Regulatory Information

Studies a U.S. FDA-regulated Drug Product	No Data Available
Studies a U.S. FDA-regulated Device Product	No Data Available
Product Exported from the U.S	No Data Available
FDA Regulated Intervention?	Yes
Section 801?	Yes
DMC Appointed?	No
IND/IDE Study?	Yes

Human Subject Safety

Board Approval Status	Submitted, approved
Board Approval Number	12/15/2022

IND/IDE						
Type	Grantor	Number	Holder Type	Holder	Availability of Expanded Access	Expanded Access Record
IND	CDER	146610	Organization		Unknown	

NIH Grants			
Funding Mechanism	NIH Institution Code	Serial Number	NCI Division/Program Code
U10	CA	180886	CTEP

Data Table 4 Information	
Funding Category	National
Funding Sponsor/Source	Children's Oncology Group
Anatomic Site Code	
Myeloid and Monocytic Leukemia	

Collaborators	
Name	Role
National Cancer Institute	Funding Source

Disease/Condition
Name
Recurrent Acute Myeloid Leukemia
Refractory Acute Myeloid Leukemia

Trial Design	
Type	Interventional
Primary Purpose	Treatment
Pragmatic Trial	No
Phase	II
Pilot Study?	No
Interventional Study Model	Single Group
Model Description	No Data Available
Number of Arms	1
Masking	No Masking
Masking Description	No Data Available

Allocation	NA
Target Enrollment	10

Eligibility Criteria	
Accepts Healthy Volunteers?	No
Sex	All
Minimum Age	24 Months
Maximum Age	21 Years

Inclusion Criteria

- Patients must be >= 24 months and < 21 years of age at the time of study enrollment
- Patient must have AML with an IDH2 mutation identified from a peripheral blood or bone marrow sample at the time of diagnosis and/or relapsed/refractory disease
- Patient must have bone marrow assessment (aspiration or biopsy) with > 5% leukemic blasts by morphology and/or flow cytometry in at least one of the following clinical scenarios:
  * Second or greater relapse after chemotherapy or hematopoietic stem cell transplant (HSCT)
  * Refractory after >= 2 attempts at induction therapy
- Relapsed patients
  * Must not have received prior re-induction therapy for this relapse
  * Each block of chemotherapy (i.e., cytarabine, daunorubicin and etoposide [ADE], cytarabine and mitoxantrone [MA]) is a separate re-induction attempt
  * Donor lymphocyte infusion (DLI) is considered a re-induction attempt
- Refractory patients
  * Each attempt at induction therapy may include up to two chemotherapy courses
- Karnofsky >= 50% for patients > 16 years of age and Lansky >= 50 for patients =< 16 years of age. Patients who are unable to walk because of paralysis, but who are up in a wheelchair, will be considered ambulatory for the purpose of assessing the performance score
- Patient’s current disease state must be one for which there is no known curative therapy or therapy proven to prolong survival with an acceptable quality of life
- Evaluation of cerebrospinal fluid (CSF) is only required if there is a clinical suspicion of central nervous system (CNS) involvement by leukemia during eligibility screening. Should a patient be found to have CNS2 or CNS3 status by CSF prior to eligibility screening, patient may receive intrathecal chemotherapy > 72 hours prior to starting study drug. CNS1 status must be established before starting study drug
- Patients must have fully recovered from the acute toxic effects of all prior anti-cancer therapy and must meet the following minimum duration from prior anti-cancer directed therapy prior to enrollment. If after the required timeframe, the numerical eligibility criteria are met, e.g., blood count criteria, the patient is considered to have recovered adequately
  * Cytotoxic chemotherapy or other anti-cancer agents known to be myelosuppressive. The duration of this interval must be discussed with the study chair and the study-assigned research coordinator prior to enrollment
  ** >= 14 days must have elapsed after the completion of other cytotoxic therapy with the exception of hydroxyurea. Additionally, patients must have fully recovered from all acute toxic effects of prior therapy. NOTE: Cytoreduction with hydroxyurea must be discontinued >= 24 hours prior to the start of protocol therapy
  ** Intrathecal chemotherapy must be completed >= 72 hours prior to the start of the first cycle of treatment
  * Anti-cancer agents not known to be myelosuppressive (e.g. not associated with reduced platelet or absolute neutrophil count [ANC] counts): >= 7 days after the last dose of agent. The duration of this interval must be discussed with the study chair and the study-assigned research coordinator prior to enrollment

* Antibodies: >= 21 days must have elapsed from infusion of last dose of antibody, and toxicity related to prior antibody therapy must be recovered to grade =< 1
* Corticosteroids: If used to modify immune adverse events related to prior therapy, >= 14 days must have elapsed since last dose of corticosteroid
* Hematopoietic growth factors: >= 14 days after the last dose of a long-acting growth factor (e.g., pegfilgrastim) or 7 days for short-acting growth factor. For agents that have known adverse events occurring beyond 7 days after administration, this period must be extended beyond the time during which adverse events are known to occur. The duration of this interval must be discussed with the study chair and the study research coordinator
* Interleukins, interferons and cytokines (other than hematopoietic growth factors): >= 21 days after the completion of interleukins, interferon or cytokines (other than hematopoietic growth factors)
* Stem cell Infusions (with or without total body irradiation [TBI]):
** Allogeneic (non-autologous) bone marrow or stem cell transplant, or any stem cell infusion including donor lymphocyte infusion (DLI) or boost infusion:
*** >= 60 days after infusion for bone marrow or stem cell transplant and
*** >= 4 weeks after infusion for any stem cell infusion including DLI or boost infusion
*** There must be no evidence of graft versus host disease (GVHD)
** Autologous stem cell infusion including boost infusion: >= 42 days
* Cellular Therapy: >= 42 days after the completion of any type of cellular therapy (e.g. modified T cells, natural killer [NK] cells, dendritic cells, etc.)
* XRT/external beam irradiation including protons: >= 14 days after local XRT; >= 150 days after TBI, craniospinal XRT or if radiation to >= 50% of the pelvis; >= 42 days if other substantial bone marrow (BM) radiation
* Radiopharmaceutical therapy (e.g., radiolabeled antibody, 131I-metaiodobenzylguanidine [MIBG]): >= 42 days after systemically administered radiopharmaceutical therapy
* Study-specific limitations on prior therapy: small molecule investigational agents: >= 14 days or > 5 half-lives must have elapsed from the last dose of the agent, whichever is greater

- Platelet count >= 20,000/mm^3 (may receive platelet transfusions)
- Hemoglobin >= 8.0 g/dL at baseline (may receive red blood cell [RBC] transfusions)
- Creatinine clearance or radioisotope glomerular filtration rate [GFR] >= 70 ml/min/1.73 m^2 or a serum creatinine based on age/gender as follows:
  * Age: Maximum serum creatinine (mg/dL)
  ** 2 to < 6 years: 0.8 (male and female)
  ** 6 to < 10 years: 1 (male and female)
  ** 10 to < 13 years: 1.2 (male and female)
  ** 13 to < 16 years: 1.5 (male); 1.4 (female)
  ** >= 16 years: 1.7 (male); 1.4 (female)
- Bilirubin (sum of conjugated + unconjugated) =< 1.5 x upper limit of normal (ULN) for age
- Serum glutamate pyruvate transaminase (SGPT) (alanine aminotransferase [ALT]) =< 225 U/L. For the purpose of this study, the ULN for SGPT is 45 U/L
- Serum albumin >= 2 g/dL
- Left ventricular ejection fraction of >= 50% by echocardiogram
- Regulatory Requirements
  * All patients and/or their parents or legal authorized representatives must sign a written informed consent. Assent, when appropriate, will be obtained according to institutional guidelines
  * All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met

Exclusion Criteria

- AML associated with Down syndrome or t(15;17) is not eligible for study
- Pregnant or breast-feeding women will not be entered on this study due to risks of fetal and teratogenic adverse events as seen in animal/human studies. Pregnancy tests must be obtained

in girls who are post-menarchal. Males or females of reproductive potential may not participate unless they have agreed to use an effective contraceptive method for the duration of study therapy and for 2 months after the last dose of enasidenib. Abstinence is an acceptable method of birth control. It is not known if enasidenib is present in breast milk. Breastfeeding is not recommended during therapy or for at least 30 days after the last dose of enasidenib

- Concomitant Medications:
  * Corticosteroids: Patients receiving corticosteroids who have not been on a stable or decreasing dose of corticosteroid for at least 7 days prior to enrollment are not eligible. If used to modify immune adverse events related to prior therapy, >= 14 days must have elapsed since last dose of corticosteroid. The use of corticosteroids to manage the side effect of IDH inhibitor-associated differentiation syndrome (IDH-DS), is permitted on study
  * Investigational drugs: Patients who are currently receiving another investigational drug are not eligible
  * Anti-cancer agents: Patients who are currently receiving other anti-cancer agents are not eligible (except leukemia patients receiving hydroxyurea, which may be continued until 24 hours prior to start of protocol therapy; the use of hydroxyurea to manage the side effect of IDH-DS, is permitted on study)
  * Anti-GVHD agents post-transplant: Patients who are receiving cyclosporine, tacrolimus or other agents to prevent graft-versus-host disease post bone marrow transplant are not eligible for this trial
- Patients must be able to swallow intact tablets whole or use the alternate enasidenib formulation.
  * Patients with known hypersensitivity to any of the components of enasidenib are not eligible.
  * Patients with prior exposure to enasidenib or another IDH2 inhibitor are not eligible.
  * Patients taking the following drugs will be excluded from study entry unless these drugs are discontinued or patients are transferred to a medically acceptable alternative > 5 half-lives before the first dose of enasidenib.
  ** Drugs with a narrow therapeutic range that are sensitive substrates of the following cytochrome P450 (CYP) enzymes: CYP2C8 (e.g. paclitaxel), 2C9 (e.g. phenytoin and warfarin), 2C19 (e.g. s-mephenytoin), 2D6 (e.g. thioridazine), and 1A2 (e.g. theophylline and tizanidine).
  ** Breast cancer resistant protein (BCRP) transporter-sensitive substrate rosuvastatin
- Patients with the following leukemia complications are not eligible for this trial:
  * No intrathecal chemotherapy is permitted on study. Prior to study enrollment, cerebrospinal fluid (CSF) evaluation is only required if there is a clinical suspicion for CNS leukemia. Clinical signs of CNS leukemia (such as facial nerve palsy, brain/eye involvement or hypothalamic syndrome) are not eligible for this trial
  * Immediately life-threatening, severe complications of leukemia including uncontrolled bleeding, pneumonia with hypoxia or shock, and/or disseminated intravascular coagulation
- Patients who have received a prior solid organ transplantation are not eligible
- Infection: Patients who have an uncontrolled infection or patients with known human immunodeficiency virus (HIV) or active hepatitis B or C are not eligible
- Patients who in the opinion of the investigator may not be able to comply with the safety monitoring requirements of the study are not eligible

Intervention(s)

Type	Name	Alternate Name	Description
Drug	Enasidenib	1446502-11-9, AG-221, CC-90007 Free Base, ENASIDENIB	Given PO
Drug	Enasidenib Mesylate	1650550-25-6,	Given PO

		2-Methyl-1-[(4-[6-(trifluoromethyl)pyridin-2-yl]-6-{[2-(trifluoromethyl)pyridin-4-yl]amino}-1,3,5-triazin-2-yl)amino]propan-2-ol Methanesulfonate, 2-Propanol, 2-Methyl-1-((4-(6-(trifluoromethyl)-2-pyridinyl)-6-((2-(trifluoromethyl)-4-pyridinyl)amino)-1,3,5-triazin-2-yl)amino)-, Methanesulfonate (1:1), AG-221 Mesylate, CC-90007, ENASIDENIB MESYLATE, Enasidenib Methanesulfonate, Idhifa	
Procedure/Surgery	Bone Marrow Aspiration	Bone Marrow Aspiration, bone marrow aspiration	Undergo bone marrow aspiration
Procedure/Surgery	Bone Marrow Biopsy	Biopsy of Bone Marrow, Biopsy, Bone Marrow, bone marrow biopsy, Bone Marrow Biopsy	Undergo bone marrow biopsy
Procedure/Surgery	Biospecimen Collection	Biological Sample Collection, Biological Sample Collection, Biospecimen Collected, Biospecimen Collection, Specimen Collection	Undergo collection of blood

Arm/Group(s)	
Type	Experimental
Label	Treatment (enasidenib)
Description	Patients receive enasidenib PO QD on days 1-28. Treatment repeats every 28 days for up to 12 cycles in the absence of disease progression or unacceptable toxicity. Patients also undergo bone marrow aspiration and/or biopsy and collection of blood on study.
Intervention(s)	

Type	Name	Alternate Name	Description
Drug	Enasidenib	1446502-11-9, AG-221, CC-90007 Free Base, ENASIDENIB	Given PO
Drug	Enasidenib Mesylate	1650550-25-6, 2-Methyl-1-[(4-[6-(trifluoromethyl)pyridin-2-yl]-6-{[2-(trifluoromethyl)pyridin-4-yl]amino}-1,3,5-triazin-2-yl)amino]propan-2-ol Methanesulfonate, 2-Propanol, 2-Methyl-1-((4-(6-(trifluoromethyl)-2-pyridinyl)-6-((2-(trifluoromethyl)-4-pyridinyl)amino)-1,3,5-triazin-2-yl)amino)-, Methanesulfonate (1:1), AG-221 Mesylate, CC-90007, ENASIDENIB MESYLATE, Enasidenib Methanesulfonate, Idhifa	Given PO
Procedure/Surgery	Bone Marrow Aspiration	Bone Marrow Aspiration, bone marrow aspiration	Undergo bone marrow aspiration
Procedure/Surgery	Bone Marrow Biopsy	Biopsy of Bone Marrow, Biopsy, Bone Marrow, bone marrow biopsy, Bone Marrow Biopsy	Undergo bone marrow biopsy
Procedure/Surgery	Biospecimen Collection	Biological Sample Collection, Biological Sample Collection, Biospecimen Collected, Biospecimen Collection, Specimen Collection	Undergo collection of blood

Primary Outcome Measures		
Title	Description	Time Frame
Incidence of dose limiting toxicities of enasidenib	Frequencies (%) of patients with a dose limiting toxicity stratified by dose level.	Up to 1 year after last dose of study drug
Area under the plasma	A descriptive analysis of the	Up to 120 days

concentration versus time curve of enasidenib	area under the plasma concentration versus time curve of enasidenib including median, minimum and maximum by dose level.	
Total plasma clearance of enasidenib	A descriptive analysis of the total plasma clearance of enasidenib including median, minimum and maximum by dose level.	Up to 120 days
Elimination half-life of enasidenib	A descriptive analysis of the elimination half-life of enasidenib including median, minimum and maximum by dose level.	Up to 120 days
Maximum concentration of enasidenib	A descriptive analysis of the maximum concentration of enasidenib including median, minimum and maximum by dose level.	Up to 120 days

Secondary Outcome Measures		
Title	Description	Time Frame
Plasma 2-HG levels of enasidenib	A descriptive analysis of the plasma 2-HG levels of enasidenib including median, minimum and maximum by dose level.	Up to 120 days
Overall Response Rate of enasidenib	Frequency (%) of patients with at least partial response by dose level.	Up to 2 years
Composite complete remission rate (complete remission [CR]/ CR with incomplete hematologic recovery [CRi])	Will be reported in a table as frequency of response (%) for total overall response rate (ORR) by dose level.	Up to 1 year after last dose of study drug
Time to response of enasidenib	Median time to response with 95% confidence interval.	From the date of first dose to the date of first documented response, assessed up to 1 year after last dose of study drug
Time to complete remission of enasidenib	Median time to remission with 95% confidence interval.	From the date of first dose to the date of first documented CR, assessed up to 1 year after last dose of study drug
Duration of response of enasidenib	Median duration of response with 95% confidence interval.	From the date of first documented response to the

		date of first documented confirmed disease progression/relapse, or death, whichever occurs first, assessed up to 1 year
Duration of complete response of enasidenib	Median duration of remission with 95% confidence interval.	From the date of first documented CR to the date of first documented confirmed disease progression/relapse, or death, whichever occurs first, assessed up to 1 year after last dose of study drug
Event-free survival of enasidenib	Median time to event with 95% confidence interval.	From the date of first dose to the date of documented confirmed disease progression/relapse, or death, whichever occurs first, assessed up to 1 year after last dose of study drug
Overall survival of enasidenib	Median time to death with 95% confidence interval.	From the patient's first dose to the date of the death, or the last date the patient was known to be alive, assessed up to 1 year after last dose of study drug

Markers					
Marker Name	Evaluation Type	Assay Type	Biomarker Use	Biomarker Purpose	Specimen Type
2-HG (2HG; 2-HG; Alpha-Hydroxyglutarate; 2-Hydroxypentanedioic Acid; Alpha-Hydroxyglutaric Acid; Pentanedioic Acid, 2-Hydroxy-; 2-Hydroxyglutaric Acid; 2-Hydroxyglutarate; 2-Hydroxy-Pentanedioic Acid)	Level/Quantity	Unspecified	Integrated	Response Assessment	Blood
Blasts 5-25	Level/Quantity	Unspecified	Integrated	Response	Bone Marrow

Percent of Bone Marrow Nucleated Cells				Assessment	
Blasts More than 5 Percent of Bone Marrow Nucleated Cells (Blasts Greater than 5 Percent of Bone Marrow Nucleated Cells; Blasts Over 5 Percent of Bone Marrow Nucleated Cells)	Level/Quantity	Flow Cytometry	Integral	Eligibility Criterion - Inclusion	Bone Marrow
Blasts Under 5 Percent of Bone Marrow Nucleated Cells (Blasts Less than 5 Percent of Bone Marrow Nucleated Cells)	Level/Quantity	Unspecified	Integrated	Response Assessment	Bone Marrow
Bone Marrow Blasts Decreased by 50 Percent or More Compared to Pretreatment Level (Decrease of Pretreatment Bone Marrow Blast Percentage by at Least 50 Percent; Decrease of Pretreatment Bone Marrow Blast Percentage by at Least 50)	Level/Quantity	Unspecified	Integrated	Response Assessment	Bone Marrow
IDH2 Gene	Genetic	Unspecified	Integral	Eligibility	Blood, Bone

Mutation (Isocitrate Dehydrogenase (NADP(+)) 2, Mitochondrial Gene Mutation; IDH2 Mutation; Isocitrate Dehydrogenase 1 (NADP+), Mitochondrial Gene Mutation)	Analysis			Criterion - Inclusion	Marrow

Participating Sites				
PO ID	Facility	Contact	Recruitment Status & Date(s)	Investigator(s)
66945	Alfred I duPont Hospital for Children, Wilmington, DE 19803 USA	Site Public Contact, email: Allison.bruce@nemours.org, phone: 302-651-5572	Active as of 02/01/2023	• Scott Bradfield - Principal Investigator
29135	Arkansas Children's Hospital, Little Rock, AR 72202-3591 USA	Site Public Contact, email: , phone: 501-364-7373	Active as of 02/01/2023	• David Becton - Principal Investigator
133247	C S Mott Children's Hospital, Ann Arbor, MI 48109 USA	Site Public Contact, email: , phone: 800-865-1125	Active as of 02/01/2023	• Rajen Mody - Principal Investigator
9858	Centre Hospitalier Universitaire Sainte-Justine, Montreal, Quebec H3T 1C5 CAN	Site Public Contact, email: yvan.samson@umontreal.ca, phone: 514-345-4931	Temporarily Closed to Accrual as of 08/31/2022	• Yvan Samson - Principal Investigator
58509	Children's Hospital Colorado, Aurora, CO 80045 USA	Site Public Contact, email: josh.b.gordon@nsmtp.kp.org, phone: 303-764-5056	Active as of 02/01/2023	• Margaret Macy - Principal Investigator
25745	Children's Hospital of Alabama, Birmingham, AL 35233 USA	Site Public Contact, email: oncologyresearch@peds.uab.edu, phone: 205-638-9285	Active as of 02/01/2023	• Matthew Kutny - Principal Investigator

196933	Children's Hospital of Pittsburgh of UPMC, Pittsburgh, PA 15224 USA	Site Public Contact, email: jean.tersak@chp.edu, phone: 412-692-8570	Active as of 02/01/2023	• Andrew Bukowinski - Principal Investigator
230502	Children's Hospital of San Antonio, San Antonio, TX 78207 USA	Site Public Contact, email: bridget.medina@christushealth.org, phone: 210-704-2894	Active as of 05/16/2023	• Timothy Griffin - Principal Investigator
238382	Children's Hospital of The King's Daughters, Norfolk, VA 23507 USA	Site Public Contact, email: CCBDCresearch@chkd.org, phone: 757-668-7243	Active as of 02/01/2023	• Eric Lowe - Principal Investigator
141741	Children's Mercy Hospitals and Clinics, Kansas City, MO 64108 USA	Site Public Contact, email: rryan@cmh.edu, phone: 816-302-6808	Active as of 02/01/2023	• Kevin Ginn - Principal Investigator
65938	Children's National Medical Center, Washington, DC 20010 USA	Site Public Contact, email: , phone: 202-884-2549	Active as of 02/01/2023	• AeRang Kim - Principal Investigator
182911	Cincinnati Children's Hospital Medical Center, Cincinnati, OH 45229 USA	Site Public Contact, email: cancer@cchmc.org, phone: 513-636-2799	Active as of 02/01/2023	• Joseph Pressey - Principal Investigator
160485	Hackensack University Medical Center, Hackensack, NJ 07601 USA	Site Public Contact, email: , phone: 201-996-2879	Active as of 02/01/2023	• Jing Chen - Principal Investigator
125217	Johns Hopkins University/Sidney Kimmel Cancer Center, Baltimore, MD 21287 USA	Site Public Contact, email: jhcccro@jhmi.edu, phone: 410-955-8804	Active as of 02/01/2023	• Alan Friedman - Principal Investigator
65850	MedStar Georgetown University Hospital, Washington, DC 20007 USA	Site Public Contact, email: , phone: 202-444-2223	Closed to Accrual as of 11/17/2022	• Nina Kadan-Lottick - Principal Investigator
71176	Nicklaus Children's Hospital, Miami, FL	Site Public Contact, email: ,	Active as of 05/30/2023	• Ziad Khatib - Principal

	33155 USA	phone: 888-624-2778		Investigator
105447	Riley Hospital for Children, Indianapolis, IN 46202 USA	Site Public Contact, email: , phone: 800-248-1199	Active as of 02/01/2023	• Sandeep Batra - Principal Investigator
60830	Rocky Mountain Hospital for Children-Presbyterian Saint Luke's Medical Center, Denver, CO 80218 USA	Site Public Contact, email: , phone: 303-839-6000	Active as of 02/01/2023	• Jennifer Clark - Principal Investigator
221716	Saint Jude Children's Research Hospital, Memphis, TN 38105 USA	Site Public Contact, email: referralinfo@stjude.org, phone: 888-226-4343	Active as of 02/01/2023	• Jeffrey Rubnitz - Principal Investigator
173533	State University of New York Upstate Medical University, Syracuse, NY 13210 USA	Site Public Contact, email: , phone: 315-464-5476	Active as of 02/01/2023	• Philip Monteleone - Principal Investigator
70710	University of Florida Health Science Center - Gainesville, Gainesville, FL 32610 USA	Site Public Contact, email: cancer-center@ufl.edu, phone: 352-273-8010	Closed to Accrual as of 02/01/2023	• William Slayton - Principal Investigator
190601	University of Oklahoma Health Sciences Center, Oklahoma City, OK 73104 USA	Site Public Contact, email: ou-clinical-trials@ouhsc.edu, phone: 405-271-8777	Active as of 02/21/2023	• Rene McNall-Knapp - Principal Investigator
226789	UT Southwestern/Simmons Cancer Center-Dallas, Dallas, TX 75390 USA	Site Public Contact, email: canceranswerline@UTSouthwestern.edu, phone: 214-648-7097	Active as of 02/01/2023	• Kathleen (Wiertel) Ludwig - Principal Investigator
221306	Vanderbilt University/Ingram Cancer Center, Nashville, TN 37232 USA	Site Public Contact, email: , phone: 800-811-8480	Active as of 02/01/2023	• Sara Zarnegar-Lumley - Principal Investigator