A Phase 1/2 Study of Bleximenib in Participants With Acute Leukemia (cAMeLot-1)

Status: RECRUITING

Eligibility Criteria

Age: 2 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

Phase 1: * Age 2 years and above (pediatric cohort only), all other cohorts 18 years and above * Relapsed or refractory (R/R) acute leukemia and has exhausted, or is ineligible for, available therapeutic options * Acute leukemia harboring histone-lysine N-methyltransferase 2A (KMT2A), nucleophosmin 1 gene (NPM1) or nucleoporin 98 gene or nucleoporin 214 gene (NUP98 or NUP214) alterations Phase: 2 * Participants greater than 18 years are eligible * Must have had an initial diagnosis of acute myeloid leukemia (AML) per the WHO 2022 classification criteria and have relapsed/refractory disease * AML harboring KMT2A-r (gene rearrangement/translocation) or NPM1 mutations only For Both Phase 1 and 2: * Pretreatment clinical laboratory values meeting the following criteria: (a) Hematology: white blood cell (WBC) count less than or equal to (\<=) 20*10\^9/liter (L) and (b) renal function; For adult participants, estimated or measured glomerular filtration rate greater than equal (\>=) 30 milliliter per minute (mL/min) per four variable MDRD equation. For pediatric participants an estimated or measured glomerular filtration rate \>40 mL/min per the CKiD (Chronic Kidney Disease in Children) Schwartz formula * Eastern Cooperative Oncology Group (ECOG) performance status grade of 0, 1 or 2. Pediatric participants only: Performance status \>=70 by Lansky scale (for participants less than \[\<\]16 years of age) or \>=70 Karnofsky scale (for participants \>=16 years of age) * A female of childbearing potential must have a negative highly sensitive serum beta-human chorionic gonadotropin at screening and within 48 hours prior to the first dose of study treatment * Participant must agree to all protocol required contraception requirements and avoid sperm or egg donations or freezing for future reproductive use while on study and for 90 days (males) or 6 months (females) after the last dose of study treatment

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Exclusion Criteria:

* Acute promyelocytic leukemia, diagnosis of Down syndrome associated leukemia or juvenile myelomonocytic leukemia according to World Health Organization (WHO) 2016 criteria * Active central nervous system (CNS) disease * Prior solid organ transplantation * QTc according to Fridericia's formula (QTcF) for males \>= 450 millisecond (msec) or for females \>= 470 msec. Participants with a family history of Long QT syndrome are excluded * Exclusion criteria related to stem cell transplant: a. Received prior treatment with allogenic bone marrow or stem cell transplant \<=3 months before the first dose of study treatment; b. Has evidence of graft versus host disease; c. Received donor lymphocyte infusion \<=1 month before the first dose of study treatment; d. Requires immunosuppressant therapy (exception: daily doses \<=10 milligrams (mg) prednisone or equivalent are allowed for adrenal replacement) * Prior cancer immunotherapy within 4 weeks prior to enrollment or blinatumomab within 2 weeks prior to enrollment. Additional prior cancer therapies must not be given within 4 weeks prior to enrollment or 5 half-lives of the agent (whichever is shorter)

Conditions & Interventions

Interventions:
DRUG: Bleximenib
Conditions:
Acute Leukemias, Acute Myeloid Leukemia, Acute Lymphoblastic Leukemia

More Information

Contact(s): Study Contact - Participate-In-This-Study1@its.jnj.com
Principal Investigator:
Phase: PHASE1
IRB
Number:
System ID: NCT04811560
