A Study of Bleximenib, Venetoclax and Azacitidine For Treatment of Participants With Newly Diagnosed Acute Myeloid Leukemia (AML)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion criteria: * Be 18 years of age or older at the time of informed consent * Previously untreated lysine N-methyltransferase 2A gene rearranged (KMT2Ar) or nucleophosmin 1 gene mutated (NPM1m) acute myeloid leukemia (AML) with greater than or equal to (\> or =) 10% bone marrow blasts per 2022 international Consensus Classification criteria * Ineligible for intensive chemotherapy based on the following criteria: a) \>= 75 years of age and ineligible per physician's discretion, with Eastern Cooperative Oncology Group (ECOG) performance status of 0-2, b) \>=18 to \<75 years of age with \>= 1 of the following comorbidities: i) ECOG performance status of 2, ii) Severe cardiac disorder, iii) Severe pulmonary disorder, iv) Renal impairment, v) Moderate hepatic impairment vi) Comorbidity that, in the investigator's opinion, makes the participant unsuitable for intensive chemotherapy, which must be documented before enrollment as defined in the protocol. Ineligibility for intensive chemotherapy should be explicitly approved by a multidisciplinary team in countries in which this process is standard of care * Participants must have adequate hepatic and renal function * A female participant must agree not to be pregnant, breast-feed, plan to become pregnant and use protocol-specified contraception while enrolled in this study and for 6 months after the last dose of study treatment * A male participant must agree to use protocol-specified contraception while enrolled in this study for at least 90 days after the last dose of study treatment * Must sign an informed consent form indicating that the participant understands the purpose of, and procedures required for, the study and is willing to participate in the study Exclusion criteria: * Diagnosis of acute promyelocytic leukemia (APL) * Known active leukemic involvement of the central nervous system (CNS) * Recipient of solid organ transplant * Any cardiac disorders such as heart attack, uncontrolled/unstable chest pain, congestive heart failure, uncontrolled or symptomatic irregular heartbeat, blockage of a blood vessel to brain, or transient ischemic (decreased oxygen in tissue) attack within 6 months of randomization * Active infectious hepatitis * Live, attenuated vaccine within 4 weeks of randomization * Known allergies, hypersensitivity, or intolerance of bleximenib, azacitidine, or venetoclax excipients

Conditions & Interventions

Interventions:

DRUG: Bleximenib, DRUG: Venetoclax (VEN), DRUG: Azacitidine (AZA), DRUG: Placebo

Conditions:

Leukemia, Myeloid, Acute

More Information

Contact(s): Study Contact - Participate-In-This-Study1@its.jnj.com

Principal Investigator:

IRB

Number:

System ID: NCT06852222