A Phase 1 Study With LYT-200 in Patients With Relapsed/Refractory Acute Myeloid Leukemia (AML), or With Relapsed/Refractory, High-risk Myelodysplastic Syndrome (MDS)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients ≥ 18 years of age at the time of obtaining informed consent. * Patients with morphologically documented primary or secondary AML by the World Health Organization(WHO) criteria, whose disease is relapsed/refractory to at least one line of prior therapy, with or without an allogeneic stem cell transplant and for whom no standard therapy that may provide clinical benefit is available or for patients who decline available standard of care. * Patients with a documented diagnosis of high-risk myelodysplastic syndrome (MDS), whose disease is relapsed/refractory, post at least one line of treatment based on the revised International Prognostic Scoring System (IPSS-R) and for whom no standard therapy that may provide clinical benefit is available * Patients are able and willing to comply with study procedures as per protocol, including bone marrowbiopsies. * Patient has an Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2. * Patient must meet the following criteria as indicated on the clinical laboratory tests: oWhite blood cell (WBC) count at the time of the first dose of \< 25,000/uL. oAspartate aminotransferase or alanine aminotransferase ≤ 3 × upper limit of normal (ULN; ≤ 5.0× ULN if considered to be due to leukemic involvement). oTotal bilirubin ≤ 2 × ULN (≤ 3 × ULN if considered to be due to leukemic involvement orGilbert's syndrome). oCreatinine clearance of ≥ 60 mL/min.

Exclusion Criteria:

* Patient diagnosed with acute promyelocytic leukemia (APL). * Patient has active malignant tumors other than AML/MDS * Patient has had HSCT and meets any of the following: has undergone HSCT within the 6- month period prior to the first study dose; has ≥ Grade 2 persistent non-hematological toxicity related to the transplant donor lymphocytes infusion. * Patient has active graft versus host disease (GVHD) and patients receiving immunosuppressive treatment for GVHD. * Patient with symptomatic central nervous system (CNS) involvement of leukemia or other CNS diseases related to underlying and secondary effects of malignancy * Patient has had major surgery within 4 weeks prior to the first study dose. * Patient has congestive heart failure New York Heart Association (NYHA) class 3 or 4, or patient with a history of congestive heart failure NYHA class 3 or 4 in the past, unless a screening echocardiogram or multigated acquisition (MUGA) scan performed within 3 months prior to study entry results in a left ventricular ejection fraction (LVEF) that is ≥ 45%. * Patient has any condition which, in the Investigator's opinion, makes the patient unsuitable for study participation.

Conditions & Interventions

Interventions:
DRUG: LYT-200, DRUG: Venetoclax, DRUG: Azacitidine, DRUG: Decitabine
Conditions:
AML, Adult Recurrent, MDS
Keywords:
AML Recurrent, AML Relapsed, AML Refractory, Hematological Cancer, Gal-9, Immuno-oncology, MDS, MDS High Risk

More Information

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