MT2024-01:A First-In-Human, Open-Label, Multicenter Study of VOR33 in Patients with Acute Myeloid Leukemia who are at High-Risk for Leukemia Relapse following Hematopoietic Cell Transplantation

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 18 to 70 years old - confirmed diagnosis of acute myeloid leukemia (AML) or Myelodysplastic Syndromes (MDS) - must have a related or unrelated stem cell donor that is a match - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- prior autologous or allogeneic stem cell transplantation - active central nervous system (CNS) leukemia

•uncontrolled bacterial, viral, or fungal infections; or known human immunodeficiency virus (HIV,), Hepatitis B, or Hepatitis C infection

•women who are pregnant or breast feeding - history of cardiovascular disease including but not limited to myocardial infarction, unstable angina, stroke, or transient ischemic attack within the 6 months or congestive heart failure

Conditions & Interventions

Interventions:
Drug: Mylotarg, Biological: VOR33
Conditions:
Cancer
Keywords:
Acute, Clinics and Surgery Center (CSC), Leukemia, Myelodysplastic Syndromes, Myeloid, AML, MDS

More Information

Description: The primary objective of this study is to assess the overall safety of VOR33 in participants with acute myeloid leukemia. VOR33 is a genome-edited hematopoietic stem and progenitor cell therapy product. Other objectives of this study include assessing the safety and tolerability and identifying the maximum tolerated dose of Mylotarg, which is an antibody-drug conjugate already approved by the FDA for adult patients with acute myeloid leukemia.
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