MT2023-05: GTB-3650 (anti-CD16/IL-15/anti-CD33) Tri-Specific Killer Engager (TriKE®) for the Treatment of High Risk Myelodysplastic Syndromes (MDS) and Refractory/Relapsed Acute Myeloid Leukemia (AML)

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- at least 18 years old - diagnosis of refractory or relapsed myeloid cancer - not a candidate for potentially curative therapy, including hematopoietic stem cell transplantation, and are refractory to, intolerant of, or ineligible for therapy options that are usually given for treatment - sexually active persons of childbearing potential or persons with partners of childbearing potential must agree to use a highly effective form of contraception during study treatment and for at least 4 months after the last dose of study drug - for the Dose Finding Component Only: must agree to stay within a 60 minute drive of the Study Center through the last study visit after the first dose (29 days) - see link to clinicaltrials.gov for complete inclusion & exclusion criteria

Exclusion Criteria:

- women who are pregnant or breast feeding - candidate for hematopoietic stem cell transplant (HSCT) - known history of HIV - active Hepatitis B or Hepatitis C - known autoimmune disease requiring active treatment

Conditions & Interventions

Interventions:
Drug: GTB-360
Conditions:
Cancer
Keywords:
Acute Myeloid Leukemia, AML, Myelodysplastic Syndromes, Myeloid Malignancy

More Information

Description: The primary purpose of this study is to identify a safe dose of GTB-3650. The study also provides preliminary disease response information for larger future studies. GTB-3650 is designed to target CD33 on leukemia/MDS cells. Cancer cells must overexpress CD33 (also referred to as CD33+), a marker found in some blood/bone marrow cancers. Based on similar studies and lab studies, it is felt there is a chance of benefit from the study treatment but the duration of benefit is unknown.
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Phase: PHASE1
IRB Number: STUDY00022729

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