MT2021-01: PTCy + Sirolimus/VIC-1911 as GVHD prophylaxis in myeloablative PBSC transplantation

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

• Diagnosis of
• acute leukemia in complete remission, or
• myelodysplasia with <5% blasts, or
• myeloproliferative neoplasm/myelofibrosis with <5% marrow or circulating blasts
• chemosensitive Hodgkin or non-Hodgkin lymphoma
• Age 18 years or older
• Performance status of â‰¥ 80% Karnofsky
• Adequate organ function within 28 days of study registration defined as:
• left ventricular ejection fraction â‰¥ 45%
• pulmonary function with FEV1, FVC, and DLCO â‰¥ 50% predicted
• AST and ALT < 2 times upper limit of normal
• Total bilirubin <1.5 times the upper limit of normal. If the patient is suspected of having Gilbert syndrome, they require prior approval of the medical monitor
• creatinine clearance â‰¥ 50cc/min
• no active/uncontrolled infection
• negative HIV, HBV and HCV
• ferritin < 2000 ng/ml
• Patients able to tolerate oral medication
• Women of childbearing potential and men with partners of child-bearing potential must agree to use of contraception for the duration of treatment through 60 days after the last treatment of VIC-1911 or sirolimus
• Able to provide written voluntary consent prior to the performance of any research related tests or procedures

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Exclusion Criteria:

• HCT-CI > 4 or unable to receive myeloablative TBI
• Use of planned post-transplant maintenance therapy to begin prior to day +75. Patients may receive standard of care maintenance therapies starting at day +75 or later
• Patients with a history of hypersensitivity to any of the investigational products
• Pregnant or breastfeeding as agents used in this study are Pregnancy Category o C: Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations, and Pregnancy category D: There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. Females of childbearing potential must have a negative pregnancy test (serum or urine) within 28 days of study registration.
• Women or men of childbearing potential unwilling to take adequate precautions to avoid unintended pregnancy from the start of protocol treatment through 60 days after the last treatment of VIC-1911 or sirolimus

Conditions & Interventions

Interventions:
Drug: VIC- 1911
Conditions:
Acute Leukemia, Myelodysplastic Syndromes, Myeloproliferative Neoplasm, Lymphoma
Keywords:
VIC-1911, PTCy, Myeloablative, Allogeneic, Clinics and Surgery Center (CSC)

More Information

Description: The primary objective of this study is to determine the optimal dose of VIC-1911 when given in combination with standard immunosuppressive therapy in adult patients undergoing myeloablative stem cell transplantation.
Contact(s): Holly Franceen - hfrancee@umn.edu
Principal Investigator: Shernan Holtan
Phase: Phase 1/Phase 2
IRB Number: STUDY00015049
System ID: NCT05120570

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