MT2023-22: Phase 1/2 Study of IDP-023 as a Single Agent and in Combination with Antibody Therapies in Patients with Advanced Hematologic Cancers

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- diagnosis of Multiple Myeloma (MM) that has relapsed or is refractory disease after 3 or more prior lines of therapy - OR Non-Hodgkin Lymphoma (NHL) that has relapsed or is refractory after 2 or more lines of chemotherapy - restricted in physically strenuous activity but able to walk and carry out work of a light or sedentary nature, e.g., light house work, office work

Exclusion Criteria:

- significant cardiac disease - Human immunodeficiency virus (HIV) infection, active hepatitis B infection, or hepatitis C infection - untreated central nervous system, epidural tumor metastasis, or brain metastasis

Conditions & Interventions

Interventions:
Drug: Cyclophosphamide, Drug: Daratumumab, Drug: Fludarabine, Drug: IDP-023, Drug: Interleukin-2, Drug: Mesna, Drug: Rituximab
Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), MM, Multiple Myeloma, NHL, Refractory Multiple Myeloma, Refractory Non-Hodgkin Lymphoma

More Information

Description: There are 2 phases to this clinical research study: Phase 1 (dose escalation) and Phase 2 (dose expansion). The goal of Phase 1 is to find the recommended dose of the study drug IDP-023 that can be given alone (referred to as a “monotherapy”), with or without interleukin-2 (IL-2) and in combination with another anti-cancer drug, either daratumumab in subjects with relapsed/refractory MM or rituximab in subjects with relapsed/refractory NHL. The goal of Phase 2 is to learn if the recommended dose of IDP-023 found in Phase 1 with or without IL-2 can help to control advanced MM or NHL when given in combination with daratumumab or rituximab, respectively.
Study Contact: Madison Barry - barry237@umn.edu
Principal Investigator: Aimee Merino
IRB Number: STUDY00019972