

MT2020-08 A Phase 1/1b Open-label, Dose-escalation, Dose-expansion, Parallel Assignment Study to Evaluate the Safety and Clinical Activity of PBCAR0191 (azercabtagene zapreleucel or azer-cel), in Subjects with Relapsed/Refractory (r/r) Non-Hodgkin Lymphoma (NHL) and r/r B-cell Acute Lymphoblastic Leukemia (B-ALL)

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 Non-Hodgkin Lymphoma - received at least 2, but no more than 7 prior chemotherapy-containing treatment regimens - previously treated with CD19-directed autologous CAR T therapies have received no more than 2 lines of therapy after administration of their previous CAR T product - restricted in strenuous activity but able to walk and able to carry out light work e.g., light house work, office work - adequate bone marrow, renal, hepatic, pulmonary, and cardiac function (study staff will review)

Exclusion Criteria:

- prior or active CNS disease - uncontrolled and serious fungal, bacterial, viral, protozoal, or other infection - active hepatitis B or hepatitis C - any known uncontrolled cardiovascular disease - contact study staff for additional exclusion criteria

Conditions & Interventions

Interventions:

Biological: Azer-cel, Drug: Bendamustine, Drug: Cyclophosphamide, Drug: Fludarabine, Drug: IL-2

Conditions:

Cancer

Keywords:

Non-Hodgkin Lymphoma, Clinics and Surgery Center (CSC)

More Information

Description: The purpose of this research study is to obtain information on the safety and effectiveness of PBCAR0191 to treat certain types of cancers, such as Non-Hodgkin Lymphoma and B-cell Acute Lymphoblastic Leukemia. It is made from a type of blood cells known as T cells. The T cells in PBCAR0191 came from people who have donated their blood. The donated T cells have been genetically changed, so that they may be able to kill specific cancer cells commonly present in Non-Hodgkin Lymphoma and B-cell Acute Lymphoblastic Leukemia.

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