A Study to Evaluate Glofitamab Monotherapy and Glofitamab + Chemoimmunotherapy in Pediatric and Young Adult Participants With Relapsed/Refractory Mature B-Cell Non-Hodgkin Lymphoma

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 months to 30 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Age 6 months to < 18 years at the time of signing Informed Consent for Cohort A Part 1 and Cohort B of the study, and age 6 months to < 30 years old at the time of signing Informed Consent for Cohort A Part 2 of the study
- Histologically re-confirmed diagnosis, via tissue biopsy, or bone marrow aspirate, pleural effusion, or ascites, prior to study entry of aggressive mature B-NHL that expresses CD20 (reconfirmed by IHC or flow cytometry if IHC is not possible), including BL, BAL (mature B-cell leukemia FAB L3), DLBCL, and PMBCL, at the time of first R/R disease for Cohort A and second or greater R/R disease for Cohort B
- Refractory or relapsed disease (i.e., prior treatment was ineffective or intolerable) following first-line standard-of-care chemoimmunotherapy for Cohort A and following at least two prior systemic chemoimmunotherapy regimens and who have exhausted all available established therapies for Cohort B
- Measurable disease, defined as: At least one bi-dimensionally measurable nodal lesion, defined as > 1.5 cm in its longest dimension, or at least one bi dimensionally measurable extranodal lesion, defined as > 1.0 cm in its longest dimension; or percentage of bone marrow involvement with lymphoma cells defined by cytomorphological analysis of bone marrow aspirates
- Adequate performance status, as assessed according to the Lansky or Karnofsky Performance Status scales: Participants < 16 years old: Lansky Performance Status ≥ 50%; Participants ≥ 16 years old: Karnofsky Performance Status ≥ 50%
- Adequate bone marrow, liver, and renal function
- Negative test results for acute or chronic hepatitis B virus (HBV), hepatitis C virus (HCV)
- Negative HIV test at screening, with the following exception: Individuals with a positive HIV test at screening are eligible provided they are stable on anti-retroviral therapy for at least 4 weeks, have a CD4 count ≥200/uL, have an undetectable viral load, and have not had a history of opportunistic infection attributable to AIDS within the last 12 months
- Negative SARS-CoV-2 antigen or PCR test within 7 days prior to enrollment
- Participants and/or caregivers who are willing and able to complete clinical outcome assessments throughout the study using either paper or interviewer methods

Exclusion Criteria:

- Isolated CNS disease of mature B-NHL without systemic involvement, and primary CNS lymphoma
- Receipt of glofitamab prior to study enrollment
- Ongoing adverse events from prior anti-cancer therapy that were not resolved to Grade ≤ 1 (exceptions: alopecia, Grade 2 peripheral neuropathy)
- Grade ≥ 3 adverse events, with the exception of Grade 3 endocrinopathy managed with replacement therapy
- Participants with active infections which are not resolved prior to Day 1 of Cycle 1
- Prior solid organ transplantation
- Known or suspected history of hemophagocytic lymphohistiocytosis (HLH), or chronic active Epstein-Barr viral infection (CAEBV)
- Active autoimmune disease requiring treatment
- History of severe allergic or anaphylactic reactions to monoclonal antibody therapy (or recombinant antibody-related fusion proteins) or known sensitivity or allergy to murine products, except if the participant was able to safely receive it after initial administration (consider consultation with Medical Monitor)
- History of confirmed progressive multifocal leukoencephalopathy
- Current or past history of uncontrolled non-malignant CNS disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease
- Evidence of significant and uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results
- Major surgery or significant traumatic injury < 28 days prior to the obinutuzumab pretreatment infusion (excluding biopsies) or anticipation of the need for major surgery during study treatment
- Administration of a live, attenuated vaccine within 4 weeks before the start of study treatment (obinutuzumab pretreatment) or at any time during the study treatment period and within 12 months after end of study treatment
- Participants with any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that would contraindicate the use of an investigational drug

Conditions & Interventions

Interventions:
DRUG: Obinutuzumab, DRUG: Glofitamab, DRUG: Rituximab, DRUG: Ifosfamide, DRUG: Carboplatin, DRUG: Etoposide, DRUG: Tocilizumab
Conditions:
Mature B-Cell Non-Hodgkin Lymphoma
Keywords:
Relapsed, Refractory, Pediatrics, B-NHL

More Information

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Description:
The purpose of this study is to evaluate the safety and efficacy of glofitamab, as monotherapy and in combination with a standard chemoimmunotherapy regimen: rituximab, ifosfamide, carboplatin, and etoposide (R-ICE) in pediatric and young adult participants with relapsed and refractory (R/R) mature B-cell non-Hodgkin lymphoma (B-NHL).

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