

Study of the Adverse Events and Change in Disease State of Pediatric Participants (and Young Adults Between the Ages of 18-25) With Relapsed/Refractory Aggressive Mature B-cell Neoplasms Receiving Subcutaneous (SC) Injections of Epcoritamab

Status: Recruiting

Eligibility Criteria

Age: 1 year to 25 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- Participants ≥ 1 and < 18 years old at time of primary diagnosis with Burkitt's or Burkitt-like lymphoma/leukemia, diffuse large B-cell lymphoma (DLBCL), or other aggressive mature (CD20+) B-cell lymphomas. Participants up to 25 years of age with Burkitt's or Burkitt-like lymphoma/leukemia are also eligible.
- Disease pathologically confirmed (tumor tissue) by local testing.
- Relapsed or primary refractory disease meeting any of the following criteria:
- Progressive disease at any time during second-line chemoimmunotherapy (CIT).
- Best response of stable disease (SD) after a minimum of 2 cycles of second-line CIT.
- Best response of partial response (PR) after a minimum of 3 cycles of second-line CIT.
- Complete Response (CR) after a minimum of 3 cycles of second-line CIT therapy but unfit or ineligible for consolidation with cell therapy.
- Not in CR and unable to initiate or tolerate (i.e., must discontinue) second-line CIT.
- Have received cell therapy (allogeneic or autologous transplant or chimeric antigen receptor T-cell (CAR-T) therapy) as consolidation but have not obtained or maintained a CR.
- Recovery from toxic effects of prior chemoimmunotherapy.
- Performance status by Lansky (< 16 years old at evaluation) or Karnofsky (≥ 16 years old at evaluation) score ≥ 50 or Eastern Cooperative Oncology Group (ECOG) score ≤ 2 .
- Adequate bone marrow, hepatic, and renal function.

Exclusion Criteria:

- Known central nervous system (CNS) involvement by lymphoma at screening as confirmed by screening magnetic resonance imaging (MRI)/computed tomography (CT)/positron emission tomography (PET) brain scans (participants with evidence of CNS disease only in the cerebrospinal fluid (CSF) will be eligible).
- Other malignancy requiring therapy.
- Currently receiving anti-cancer therapy, including chemotherapy (excluding intrathecal therapy), radiotherapy, small molecules, monoclonal antibodies, cell therapy, or other investigational agents.

Conditions & Interventions

Interventions:

Drug: Epcoritamab

Conditions:

Non-Hodgkin Lymphoma

Keywords:

Non-hodgkin Lymphoma, ABBV-GMAB-3013, Epcoritamab, Burkitt's or Burkitt-like Lymphoma/Leukemia, Diffuse Large B-cell Lymphoma, Aggressive Mature (CD20+) B-cell Lymphoma, Cancer, Relapsed/Refractory Aggressive Mature B-cell Neoplasms

More Information

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Principal Investigator:

Phase: Phase 1

IRB

Number:

System ID: NCT05206357

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