Study to Compare Axicabtagene Ciloleucel With Standard of Care Therapy as First-line Treatment in Participants With High-risk Large B-cell Lymphoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

* Histologically confirmed large B cell lymphoma (LBCL) based on 2016 World Health Organization (WHO) classification by local pathology lab assessment, including of the following: * Diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) * High-grade B-cell lymphoma (HGBL) * Note: Transformed DLBCL from follicular lymphoma or from marginal zone lymphoma is eligible if no prior treatment with anthracycline-containing regimen. * High-risk disease defined as an International Prognostic Index (IPI) score of 4 or 5 at initial diagnosis. * Have received only 1 cycle of rituximab plus chemotherapy (R-chemotherapy). * Adequate bone marrow, renal, hepatic, pulmonary, and cardiac function. * Females of childbearing potential must have a negative serum or urine pregnancy test. Key

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Exclusion Criteria:

* The following WHO 2016 subcategories by local assessment: * T-cell/histiocyte-rich LBCL * Primary DLBCL of the central nervous system (CNS) * Primary mediastinal (thymic) LBCL * B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and classical Hodgkin lymphoma * Burkitt lymphoma * History of Richter's transformation of chronic lymphocytic leukemia * Presence of detectable cerebrospinal fluid (CSF)-malignant cells, brain metastases, or a history of CNS involvement of lymphoma. * Presence of cardiac lymphoma involvement. * Any prior treatment for LBCL other than the 1 cycle of R-chemotherapy. * History of severe immediate hypersensitivity reaction to any of the agents used in this study. * Presence of CNS disorder. History of stroke, transient ischemic attack, or posterior reversible encephalopathy syndrome (PRES) within 12 months prior to enrollment. * History of acute or chronic active hepatitis B or C infection. * Positive for human immunodeficiency virus (HIV) unless taking appropriate anti-HIV medications, with an undetectable viral load by PCR and with a cluster of differentiation 4 (CD4) count \> 200 cells/uL. * Medical conditions or residual toxicities from prior therapies likely to interfere with assessment of safety or efficacy of study treatment. Please refer to protocol for further details. * History of clinically significant cardiac disease within 12 months before enrollment. * History of any medical condition requiring maintenance systemic immunosuppression/systemic disease modifying agents within the last 2 years. Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Conditions & Interventions

Interventions:

BIOLOGICAL: Axicabtagene Ciloleucel, DRUG: Cyclophosphamide, DRUG: Fludarabine, DRUG: Etoposide, DRUG: Rituximab, DRUG: Doxorubicin, DRUG: Vincristine, DRUG: Prednisone

Conditions:

High-risk Large B-cell Lymphoma (LBCL)

More Information

Contact(s): Medical Information - medinfo@kitepharma.com

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT05605899
