Study to Compare the Effectiveness and Safety of Golcadomide Plus R-CHOP vs Placebo Plus R-CHOP in Participants With Previously Untreated High-risk Large B-cell Lymphoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

\text{\chick_Histologically confirmed (per local evaluation) diagnosis of de novo, previously untreated large B-cell lymphoma (LBCL) according to 2022 world health organization (WHO) classification including: i) Diffuse large B-cell lymphoma (DLBCL), not otherwise specified \[\text{[including germinal center B-cell (GCB) and activated B-cell (ABC) types\] ii) High-grade B-cell lymphoma, with MYC and BCL2 rearrangements (HGBL-MYC/BCL2 double-hit lymphomas) iii) High-grade B-cell lymphoma, not otherwise specified iv) T-cell/histiocyte/rich large B-cell lymphoma (THRLBCL) v) Epstein-Barr virus + DLBCL * International Prognostic Index (IPI) score 1 or 2 with lactate dehydrogenase (LDH) \> 1.3 x upper limit of normal (ULN) and/or bulky disease defined as single lesion of ≥ 7 cm OR IPI ≥ 3. * Measurable disease defined by at least 1 fluorodeoxyglucose (FDG)-avid lesion for FDG-avid subtype and 1 bi-dimensionally measurable (\> 1.5 cm in longest diameter) disease by computed tomography (CT) or magnetic resonance imaging (MRI), as defined by the Lugano classification. * Must have Ann Arbor Stage II-IV disease.

Exclusion Criteria:

* Any significant medical condition, active infection, laboratory abnormality, or psychiatric illness that would prevent the participant from participating in the study. * Any other subtype of lymphoma. Cases of primary mediastinal (thymic) large B-cell lymphoma (PMBCL), primary cutaneous DLBCL-leg type, Grade 3b FL, indolent lymphoma transformed to large B-cell lymphoma (LBCL), Anaplastic lymphoma kinase (ALK) positive large B-cell lymphoma, primary effusion lymphoma, and Burkitt lymphoma. * Documented or suspected central nervous system (CNS) involvement by lymphoma. * Other protocol-defined Inclusion/Exclusion criteria apply.

Conditions & Interventions

Interventions:

DRUG: Golcadomide, DRUG: Placebo, DRUG: Rituximab, DRUG: Cyclophosphamide, DRUG: Doxorubicin, DRUG: Vincristine, DRUG: Prednisone

Conditions:

Large B-cell Lymphoma

Keywords:

Lymphoma, Large B-Cell, Lymphoma, BMS-986369, CC-99282, DLBCL

More Information

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Principal Investigator: Phase: PHASE3

IRB Number:

System ID: NCT06356129

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