ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)B-cell Non-Hodgkin Lymphoma

A Phase Ib/II Study Investigating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Mosunetuzumab (BTCT4465A) in Combination With CHOP or CHP-Polatuzumab Vedotin in Participants With B-Cell Non-Hodgkin Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT03677141 2018-001039-29 GO40515

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase Ib/II, Open-Label, Multicenter, Randomized, Controlled Study Investigating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Mosunetuzumab (BTCT4465A) in Combination With CHOP or CHP-Polatuzumab Vedotin in Patients With B-Cell Non-Hodgkin Lymphoma

Trial Summary:

This study will evaluate the safety, pharmacokinetics, and preliminary efficacy of mosunetuzumab in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (M-CHOP) and, subsequently, in combination with cyclophosphamide, doxorubicin, and prednisone (CHP) plus polatuzumab vedotin (CHP-pola) in participants with relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (NHL), and in previously untreated participants with diffuse large B-cell lymphoma (DLBCL).

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT03677141 2018-001039-29 GO40515
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

Inclusion Criteria for Phase Ib and Phase II Portions

- At least one bi-dimensionally measurable nodal lesion, defined as > 1.5 cm in its longest dimension, or one bi-dimensionally measurable extranodal lesion, defined as > 1.0 cm in its longest diameter
- Eastern Cooperative Oncology Group Performance Status of 0, 1, or 2
- Adequate hematologic function

Inclusion Criteria for Phase Ib Portion

Participants must also meet the following criteria for study entry into the Phase Ib portion:

- Histologically confirmed B-cell NHL according to the World Health Organization (WHO) 2016 classification expected to express the cluster of differentiation-20 (CD20) antigen
- Relapsed or refractory (R/R) B-cell NHL after at least one prior systemic lymphoma therapy
- Treatment with at least one prior CD20-directed therapy
- Group B only: no prior treatment with polatuzumab vedotin

Inclusion Criteria for Phase II Portion

Participants must also meet the following criteria for study entry in the Phase II portion:

- Previously untreated, histologically confirmed DLBCL according to WHO 2016 classification
- International Prognostic Index (IPI) score of 2-5

Exclusion Criteria:

- Prior treatment with mosunetuzumab
- Prior allogenic stem-cell transplant
- Current Grade >1 peripheral neuropathy
- Participants with history of confirmed progressive multifocal leukoencephalopathy (PML)
- Known or suspected chronic active Epstein Barr virus (CAEBV), hepatitis B, hepatitis C (HCV), or Human Immunodeficiency Virus (HIV)
- Prior solid organ transplantation
- History of autoimmune disease
- Current or past history of central nervous system (CNS) lymphoma
- Current or past history of CNS disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease
- Significant cardiovascular disease or pulmonary disease
- Clinically significant history of liver disease
- Recent major surgery within 4 weeks before the start of C1D1, other than superficial lymph node biopsies for diagnosis

Exclusion Criteria for Phase Ib Portion

Participants who also meet any of the following criteria will be excluded from study entry in the Phase Ib portion:

- Prior treatment with chemotherapy, immunotherapy, and biologic therapy 4 weeks prior to C1D1
- Prior treatment with radiotherapy within 2 weeks prior to C1D1

- Adverse events from prior anti-cancer therapy resolved to #Grade 1 (with the exception of alopecia and anorexia)
- Prior treatment with >250 mg/m^2 doxorubicin (or equivalent anthracycline dose)

Exclusion Criteria for Phase II Portion

Participants who also meet any of the following criteria will be excluded from study entry in the Phase II portion:

- Participants with transformed lymphoma
- Prior therapy for B-cell NHL