ForPatients
by Roche

Diffuses großzelliges B-Zell-Lymphom

Eine Studie zum Vergleich der Wirksamkeit und Sicherheit von Polatuzumab Vedotin mit Rituximab-Cyclophosphamid, Doxorubicin und Prednison (R-CHP) im Vergleich zu Rituximab-Cyclophosphamid, Doxorubicin, Vincristin und Prednison (R-CHOP) bei Teilnehmenden mit diffusem großzelligem B-Zell-Lymphom

A Study Comparing the Efficacy and Safety of Polatuzumab Vedotin With Rituximab-Cyclophosphamide, Doxorubicin, and Prednisone (R-CHP) Versus Rituximab-Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in Participants With Diffuse Large B-Cell Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Aktiv, keine Rekrutierung	22 Countries	NCT03274492 2017-002023-21 GO39942

Die Informationen stammen direkt von Websites öffentlicher Register wie ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com usw. und wurden nicht modifiziert.

Official Title:

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial Comparing the Efficacy and Safety of Polatuzumab Vedotin in Combination With Rituximab and CHP (R-CHP) Versus Rituximab and CHOP (R-CHOP) in Previously Untreated Patients With Diffuse Large B-Cell Lymphoma

Trial Summary:

This Phase III, randomized, double-blind, placebo-controlled study will compare the efficacy, safety, and pharmacokinetics of polatuzumab vedotin plus R-CHP versus R-CHOP in participants with previously untreated diffuse large B-cell lymphoma (DLBCL).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03274492 2017-002023-21 GO39942
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 80 Years	No

Inclusion Criteria:

- Previously untreated participants with cluster of differentiation 20 (CD20)-positive DLBCL, including one of the following diagnoses by 2016 World Health Organization (WHO) classification of lymphoid neoplasms: DLBCL, not otherwise specified (NOS) including germinal center B-cell type, activated B-cell type; T-cell/histiocyte-rich large B-cell lymphoma; Epstein-Barr virus-positive DLBCL, NOS; anaplastic lymphoma kinase (ALK)-positive large B-cell lymphoma; human herpesvirus-8 (HHV8)-positive DLBCL, NOS; High-grade B-cell lymphoma with MYC and B-cell lymphoma 2 (BCL2) and/or B-cell lymphoma 6 (BCL6) rearrangements (double-hit or triple-hit lymphoma); High-grade B-cell lymphoma, NOS
- Availability of archival or freshly collected tumor tissue before study enrolment
- International Prognostic Index (IPI) score of 2-5
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2
- Life expectancy greater than or equal to (>/=)12 months
- Left ventricular ejection fraction (LVEF) >/= 50 percent (%) on cardiac multiple-gated acquisition (MUGA) scan or cardiac echocardiogram (ECHO)
- Adequate hematologic function
- Female participants: Agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods and refrain from donating eggs.
- Male participants: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom and agreement to refrain from donating sperm.

Exclusion Criteria:

- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies or known sensitivity or allergy to murine products
- Contraindication to any of the individual components of CHOP, including prior receipt of anthracyclines
- Prior organ transplantation
- Current Grade greater than (>) 1 peripheral neuropathy by clinical examination
- Demyelinating form of Charcot-Marie-Tooth disease
- History of indolent lymphoma
- History of follicular lymphoma grade 3B
- B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and classical Hodgkin lymphoma (grey-zone lymphoma)
- Primary mediastinal (thymic) large B-cell lymphoma
- Burkitt lymphoma
- Prior treatment with cytotoxic drugs within 5 years of screening for any condition (example [e.g.], cancer, rheumatoid arthritis) or prior use of any anti-CD20 antibody
- Prior use of any monoclonal antibody within 3 months of the start of Cycle 1
- Prior therapy for DLBCL, with the exception of nodal biopsy
- Corticosteroid use >30 mg/day of prednisone or equivalent, for purposes other than lymphoma symptom control
- Participants with central nervous system (CNS) lymphoma (primary or secondary involvement), primary effusion DLBCL, and primary cutaneous DLBCL
- Vaccination with live vaccines within 28 days prior to the start of Cycle 1
- Any investigational therapy within 28 days prior to the start of Cycle 1
- History of other malignancy that could affect compliance with the protocol or interpretation of results
- Evidence of significant, uncontrolled, concomitant diseases that could affect compliance with the protocol or interpretation of results, including significant cardiovascular disease or pulmonary disease
- Recent major surgery (within 4 weeks prior to the start of Cycle 1), other than for diagnosis

- History or presence of an abnormal electrocardiogram (ECG) that is clinically significant in the investigator's opinion, including complete left bundle branch block, second- or third-degree heart block, or evidence of prior myocardial infarction
- Known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection (excluding fungal infections of nail beds) at study enrollment or significant infections within 2 weeks before the start of Cycle 1
- Clinically significant liver disease, including active viral or other hepatitis, current alcohol abuse, or cirrhosis
- Prior radiotherapy to the mediastinal/pericardial region
- Participants with suspected active or latent tuberculosis
- Positive test results for chronic hepatitis B and hepatitis C infection
- Known history of human immunodeficiency virus (HIV) seropositive status
- Positive results for the human T-lymphotrophic 1 virus (HTLV-1)
- Participants with a history of progressive multifocal leukoencephalopathy