ForPatients
*by Roche*

Diffuse Large B-Cell Lymphoma (DLBCL)

# A Study to Evaluate the Efficacy and Safety of Polatuzumab Vedotin in Combination With Bendamustine and Rituximab Compared With Bendamustine and Rituximab Alone in Chinese Patients With Relapsed or Refractory Diffuse Large B-cell Lymphoma (R/R DLBCL).

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Terminated | 1 Country | NCT04236141 YO41543 |

*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 III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Polatuzumab Vedotin in Combination With Bendamustine and Rituximab Compared With Bendamustine and Rituximab Alone in Chinese Patients With Relapsed or Refractory Diffuse Large B-cell Lymphoma.

## *Trial Summary:*

A study to evaluate the Efficacy and Safety of Polatuzumab Vedotin in combination with BR (Bendamustine and Rituximab) compared with BR alone in Chinese participants with R/R DLBCL. Approximately 42 Chinese participants will be randomised to treatment arms in a 2:1 ratio. Randomisation will be conducted with the aid of an interactive web-based response system (IxRS).

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|---|---|
| **Hoffmann-La Roche**<br>Sponsor | **Phase 3**<br>Phase |

**NCT04236141 YO41543**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

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## *Inclusion Criteria:*

- Able to comply with the study protocol and procedures, in the investigator's judgement.
- Transplant ineligible participants with R/R DLBCL.
- Confirmed DLBCL diagnosis.
- For participants who have received prior bendamustine, a response duration > 1 year (for participants who have relapsed disease after a prior regimen).
- At least one bi-dimensionally measurable lesion, defined as > 1.5 cm in its longest dimension as measured by CT or magnetic resonance imaging (MRI).
- Availability of archival or freshly collected tumor tissue before study enrolment.
- Life expectancy of at least 24 weeks.
- ECOG Performance Status of 0, 1 or 2.
- Adequate haematologic function.
- Women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, and agreement to refrain from donating eggs.
- For men who are not surgically sterile: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, and agreement to refrain from donating sperm.
- Residence in the People's Republic of China.

## *Exclusion Criteria:*

- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies (MAbs) or recombinant antibody-related fusion proteins) or known sensitivity or allergy to murine products.
- Contraindication to bendamustine or rituximab.
- History of sensitivity to mannitol (mannitol is an excipient in bendamustine).
- Prior use of any MAb, radioimmunoconjugate, or antibody-drug conjugate (ADC) within 5 half-lives or 4 weeks, whichever is longer, before Cycle 1, Day 1.
- Treatment with radiotherapy, chemotherapy, immunotherapy, immunosuppressive therapy, or any investigational agent for the purposes of treating cancer within 2 weeks prior to Cycle 1, Day 1.
- Ongoing corticosteroid use > 30 mg/day prednisone or equivalent, for purposes other than lymphoma symptom control.
- Completion of autologous SCT within 100 days prior to Cycle 1, Day 1.
- Prior allogeneic Stem Cell Transplantation (SCT).
- Prior treatment with Chimeric Antigen Receptor (CAR) T-cell therapy.
- Eligibility for autologous SCT.
- Grade 3b Follicular Lymphoma (FL).
- History of transformation of indolent disease to DLBCL.
- Primary or secondary CNS lymphoma.
- Current Grade > 1 peripheral neuropathy.
- 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 or pulmonary disease.
- Known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection (excluding fungal infections of nail beds) at study enrollment or any major episode of infection requiring treatment with IV antibiotics or hospitalization (relating to the completion of the course of antibiotics) within 4 weeks prior to Cycle 1, Day 1.
- Participants with suspected or latent tuberculosis.
- Positive Chronic Hepatitis B (HBV) infection or Hepatitis C (HCV) infection.
- Known history of HIV infection.
- Known infection human T-cell leukemia virus 1 virus.

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- Vaccination with a live vaccine within 28 days prior to treatment.
- Recent major surgery (within 6 weeks before the start of Cycle 1, Day 1) other than for diagnosis.
- Pregnant or breastfeeding or intending to become pregnant during the study or within 12 months after the final dose of study treatment.
- Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results or renders the patient at high risk from treatment complications.

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