ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)Lymphoma

A Study on Pharmacokinetics (PK), Efficacy and Safety of Subcutaneous (SC) Versus Intravenous (IV) Rituximab, in Combination With CHOP (Cyclophosphamide, Doxorubicin, Vincristine, Prednisone) in Previously Untreated Participants With CD20 Positive Diffuse Large B-Cell Lymphoma (DLBCL)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04660799 YO42207

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 II Comparative, Open-Label, Randomized, Multicenter, China-Only Study to Investigate the Pharmacokinetics, Efficacy and Safety of Subcutaneous Rituximab Versus Intravenous Rituximab Both in Combination With CHOP in Previously Untreated Patients With CD20 Positive Diffuse Large B Cell Lymphoma

Trial Summary:

This is a multicenter China-only study to investigate the PK, efficacy and safety of SC rituximab versus IV rituximab, both in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) in previously untreated participants with CD20 positive DLBCL. Participants will be randomized to receive eight cycles of rituximab SC or rituximab IV combined with six or eight cycles of standard CHOP chemotherapy. After the end of study treatment, participants will be followed-up every 3 months for 6 months.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04660799 YO42207
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Previously untreated CD20 positive diffuse large B-cell lymphoma (DLBCL)
- Participants with an International Prognostic Index (IPI) score of 1 to 5 or IPI score of 0 with bulky disease, defined as one lesion >/=7.5 cm
- At least one bi-dimensionally measurable lesion defined as >/=1.5 cm in its largest dimension on CT scan
- Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2
- Left ventricular ejection fraction (LVEF) >/=50% on cardiac multiple-gated acquisition (MUGA) scan or cardiac echocardiogram
- A negative serum pregnancy test or a negative urine pregnancy test within 7 days prior to study treatment
- For men who are not surgically sterile, agreement to use a barrier method of contraception during the treatment period and until >/=12 months after the last dose of rituximab SC or rituximab IV or according to institutional guidelines for CHOP chemotherapy, whichever is longer, and agreement to request that their partners use an additional method of contraception
- For women of reproductive potential who are not surgically sterile, agreement to use adequate methods of contraception during the treatment period and until >/=12 months after the last dose of rituximab SC or rituximab IV or according to institutional guidelines for CHOP chemotherapy, whichever is longer
- Adequate hematologic function confirmed within 14 days prior to randomization

Exclusion Criteria:

- Transformed non-Hodgkin's lymphoma (NHL) or types of NHL other than DLBCL and its subtypes according to World Health Organization classification
- 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 therapy for DLBCL, with the exception of nodal biopsy or local irradiation or surgery for diagnosis
- Prior treatment with cytotoxic drugs or rituximab for another condition (e.g.,rheumatoid arthritis) or prior use of an anti-CD20 antibody
- Current or recent treatment with another investigational drug or participation in another investigational therapeutic study
- Ongoing corticosteroid use (>30 mg/day of prednisone or equivalent)
- Primary CNS lymphoma, blastic variant of mantle cell lymphoma, or histologic evidence of transformation to a Burkitt lymphoma, primary mediastinal DLBCL, primary effusion lymphoma, and primary cutaneous DLBCL
- History of other malignancy that could affect compliance with the protocol or interpretation of results
- Evidence of significant, uncontrolled concomitant diseases including but not limited to significant cardiovascular disease or pulmonary disease
- Any of the following abnormal laboratory values: creatinine >1.5 upper limit of normal (ULN), aspartate aminotransferase (AST) / alanine aminotransferase (ALT) >2.5ULN, total bilirubin >1.5ULN, prothrombin time - international normalized ratio (PT-INR) / partial thromboplastin time (PTT) / activated partial thromboplastin time (aPTT)>1.5ULN
- Positive test results for chronic hepatitis B (HBV) and or hepatitis C (HCV) infection; Participants with occult or prior HBV infection (defined as negative HBsAg and positive total hepatitis B core antibody [HBcAb]) may be included if HBV DNA is undetectable; Participants positive for HCV antibody are eligible only if polymerase chain reaction (PCR) is negative for HCV RNA
- Known history of human immunodeficiency virus (HIV)