ForPatients
by Roche

Non Hodgkin Lymphoma (NHL)

A clinical trial to compare mosunetuzumab plus polatuzumab vedotin with rituximab plus gemcitabine plus oxaliplatin in people with relapsed or refractory aggressive non-Hodgkin's lymphoma

A Study Evaluating Efficacy and Safety of Mosunetuzumab in Combination With Polatuzumab Vedotin Compared to Rituximab in Combination With Gemcitabine Plus Oxaliplatin in Participants With Relapsed or Refractory Aggressive B-Cell Non-Hodgkin's Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	13 Countries	NCT05171647 GO43643

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 Randomized, Open-Label, Multicenter Phase III Study Evaluating Efficacy and Safety of Mosunetuzumab in Combination With Polatuzumab Vedotin in Comparison With Rituximab in Combination With Gemcitabine Plus Oxaliplatin in Participants With Relapsed or Refractory Aggressive B-Cell Non-Hodgkin's Lymphoma

Trial Summary:

This study will assess the efficacy and safety of mosunetuzumab in combination with polatuzumab vedotin (M+P) in participants with relapsed or refractory (R/R) diffuse-large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma, transformed follicular lymphoma (trFL) and FL Grade 3B (FL3B) in comparison with a commonly used regimen in this participant population, rituximab, gemcitabine and oxaliplatin (R-GemOx).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT05171647 GO43643
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the SUNMO clinical trial work?

This clinical trial is recruiting people who have aggressive non-Hodgkin's lymphoma (NHL), according to specific criteria. In order to take part, patients must have disease that has returned after successful treatment (relapsed) or that has not responded to treatment (refractory).

The purpose of this clinical trial is to compare the effects, good or bad, of mosunetuzumab plus polatuzumab vedotin (called 'M+P' in this document) versus rituximab plus gemcitabine plus oxaliplatin (called 'R-GemOx' in this document) on patients with aggressive NHL. In this clinical trial, you will get either M+P or R-GemOx.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years old and have been diagnosed with aggressive NHL, according to specific criteria. You must have received at least one previous treatment for NHL, after which the cancer did not get better or came back.

If you have certain other medical conditions or have received certain medications or treatments, you may not be able to take part in this clinical trial. If you are pregnant or breastfeeding, or are intending to become pregnant shortly after your last dose of clinical trial treatment, you will not be able to take part in this clinical trial.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be split into two groups randomly (like tossing a coin) and given either:

- M+P treatment: mosunetuzumab, as an injection under the skin (subcutaneous) once a week for the first three weeks (Cycle 1), then once every three weeks for Cycles 2-8. You will also be given polatuzumab vedotin as an infusion into the vein once every three weeks for Cycles 1-6

OR

- R-GemOx treatment: rituximab, gemcitabine and oxaliplatin, each given as infusions into the vein every two weeks for up to eight cycles.

You will have a 2 in 3 chance (67%) of being placed in the M+P group and a 1 in 3 chance (33%) of being placed in the R-GemOx group.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatments for up to 24 weeks (roughly six months) in the M+P group or for up to 16 weeks (roughly four months) in the R-GemOx group. You will also have some additional tests and procedures, such as blood tests, for research purposes. You are free to stop this treatment at any time. After you have finished your treatment, you will still be seen regularly by the clinical trial doctor every three months for up to two and a half years (from when you started clinical trial treatment). These hospital visits will include checks to see how you have responded to the treatment and checks on any side effects that you may be having.

What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT05171647

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2
- CD20+ aggressive lymphoma as determined by the local hemopathology laboratory from the following diagnoses by 2016 World Health Organization classification of lymphoid neoplasms: DLBCL, not otherwise specified (NOS); high-grade B-cell lymphoma (NOS or double/triple hit); transformed follicular lymphoma; follicular lymphoma Grade 3b

- Have disease relapsed or refractory to at least one prior systemic therapy for aggressive non-Hodgkin's lymphoma (aNHL)
- Participants who have received only one prior line of therapy must be ineligible for autologous stem cell transplant (ASCT)
- Measurable disease
- Adequate hepatic, hematologic, and renal function
- Estimated creatinine clearance (CrCl) # 30 mL/min by Cockroft-Gault method or other institutional standard methods
- Negative HIV test at screening. Participants with a positive HIV test at screening are eligible provided that, prior to enrollment, they are stable on anti-retroviral therapy for at least 4 weeks, have a CD4 count of at least 200 microliters, have an undetectable viral load, and have not had a history of opportunistic infection attributable to AIDS within the last 12 months

Exclusion Criteria:

- Pregnant or breast feeding, or intending to become pregnant during the study or within 3 months after the final dose of mosunetuzumab, 9 months after the final dose of polatuzumab vedotin, 12 months after the final dose of rituximab, 6 months after the final dose of gemcitabine, 9 months after the final dose of oxaliplatin, and 3 months after the final dose of tocilizumab, as applicable
- Inability to comply with protocol-mandated activity restrictions
- Prior treatment with mosunetuzumab or other CD-20-directed bispecific antibodies, or R-GemOx or Gem-Ox
- Prior treatment with polatuzumab vedotin, with the following exceptions: participants who have a documented response (partial response or complete response) to polatuzumab vedotin and an absence of PD within 12 months from the last dose of polatuzumab vedotin; participants who received up to 2 doses of a polatuzumab vedotin-containing regimen as bridging to CAR-T therapy, and either has a documented disease control (stable disease, partial response, or complete response), or were not assessed for response following treatment with polatuzumab vedotin
- Contraindication to any component of the study treatment
- Grade > 1 peripheral neuropathy
- Participants with Grade > 1 persistent toxicity related to prior anti-lymphoma treatment (except for alopecia and anorexia, or other toxicities not considered a safety risk for the participant per investigator's judgment)
- Received anti-lymphoma treatments with monoclonal antibodies, radio-immunoconjugates or antibody-drug conjugates (ADCs) within 4 weeks before the first dose of study treatment
- Treatment with any chemotherapeutic agent, or treatment with any other anti-lymphoma agent (investigational or otherwise) within 4 weeks or 5 half-lives of the drug, whichever is shorter, prior to the first dose of study treatment
- Treatment with radiotherapy within 2 weeks prior to the first dose of study treatment
- ASCT within 100 days prior to the first study treatment administration
- Prior treatment with chimeric antigen receptor (CAR) T cell therapy within 30 days before the first study treatment administration
- Prior allogenic stem cell transplant (SCT)
- Have had a solid organ transplantation
- Known or suspected history of hemophagocytic lymphohistiocytosis (HLH)
- History of confirmed progressive multifocal leukoencephalopathy
- History of severe allergic or anaphylactic reactions to monoclonal antibody therapy (or recombination antibody-related fusion proteins)
- History of other malignancy that could affect compliance with the protocol or interpretation of results, with the exception of malignancies with a negligible risk of metastasis or death
- Currently have or have had a past history of central nervous system (CNS) involvement of lymphoma

- Current or past history of CNS disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease. Participants with a history of stroke who have not experienced a stroke or transient ischemic attack in the past 2 years and have no residual neurologic deficits as judged by the investigator, or with a history of epilepsy who have had no seizures in the past 2 years while not receiving any anti-epileptic medications, are allowed
- Significant cardiovascular disease such as New York Heart Association Class III or IV cardiac disease, myocardial infarction within the last 6 months, unstable arrhythmias, or unstable angina
- Significant active pulmonary disease
- Participants with active symptoms of interstitial lung disease and/or pneumonitis, or those with a history of interstitial lung disease and/or pneumonitis within 6 months prior to the first dose of study treatment
- Known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection (excluding fungal infections of the 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 2 weeks prior to the first study treatment administration
- Known or suspected chronic active Epstein-Barr virus (EBV) infection
- Recent major surgery within 4 weeks prior to the first study treatment administration
- Positive test results for chronic hepatitis B infection
- Acute or chronic hepatitis C virus (HCV) infection
- Have been administered a live, attenuated vaccine within 4 weeks before the first dose of study treatment administration or anticipation that such a live, attenuated vaccine will be required during the study
- Participants who have positive SARS-CoV-2 test within 7 days prior to enrollment (rapid antigen test result is acceptable)
- History of autoimmune disease
- Received investigational therapy, whether or not intended for lymphoma treatment, within 7 days prior to initiation of study treatment
- Clinically significant history of liver disease, including viral or other hepatitis, or cirrhosis