ForPatients
by Roche

Non Hodgkin Lymphoma (NHL)

A study to look at how safe different doses of the study medicine - DCDS0780A - were for patients with non-Hodgkin's Lymphoma that involved B cells

A Study of Escalating Doses of DCDS0780A in Participants With Relapsed or Refractory B-Cell Non-Hodgkin's Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02453087 GO29687

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:

An Open-label, Multicenter, Phase 1/1b Dose Escalation Study Evaluating the Pharmacokinetics, Safety, Tolerability, and Preliminary Efficacy of DCDS0780A, Alone or in Combination With Rituximab, or Obinutuzumab, in Patients With Relapsed/Refractory B-Cell Non-Hodgkin's Lymphoma

Trial Summary:

This open-label, multicenter, Phase 1/1b study will evaluate the safety, tolerability, and pharmacokinetics of increasing doses of DCDS0780A in participants with relapsed or refractory B-cell non-Hodgkin's lymphoma. In the combination portion of the study, the safety and tolerability of DCDS0780A in combination with rituximab or obinutuzumab will be assessed.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT02453087 GO29687
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

DCDS0780A is a new medicine known as an antibody-drug conjugate or "ADC". Patients with non-Hodgkin's Lymphoma that involved B cells received different doses

of DCDS0780A to help researchers find out which dose was safe. In a second part to this study, patients got DCDS0780A with an approved medicine called “rituximab”. Researchers wanted to know if DCDS0780A was safe when used with rituximab.

Inclusion Criteria:

- Life expectancy of at least 12 weeks
- Histologically confirmed B-cell non-Hodgkin's lymphoma that has relapsed after or failed to respond to at least one prior treatment regimen and for which no suitable therapy of curative intent or higher priority exists
- A clinical indication for treatment as determined by the investigator
- Availability of archival or freshly collected tumor tissue before study enrollment
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Fasting (greater than or equal to [>=] 8 hours) glucose less than or equal to (<=) 160 milligrams per deciliter (mg/dL)
- Participants requiring anti-diabetic medications must be on a stable dose and regimen for >=4 weeks
- Adequate hematologic function without growth factor or transfusion support
- For women who are not postmenopausal (>= 12 months of non-therapy-induced amenorrhea) or surgically sterile (absence of ovaries and/or uterus): agreement to remain abstinent or use single or combined contraceptive methods as specified in protocol
- For men: agreement to remain abstinent or use a condom plus an additional contraceptive method as specified in protocol

Exclusion Criteria:

- Prior use of any monoclonal antibody or antibody-drug conjugate within 4 weeks before Cycle 1, Day 1
- Treatment with radiotherapy, any chemotherapeutic agent, systemic steroids used as an anti-neoplastic agent, or any other investigational anti-cancer agent within 2 weeks prior to Cycle 1, Day 1
- Completion of autologous stem cell transplant within 100 days prior to Cycle 1, Day 1
- Prior allogeneic stem cell transplant
- Current or history of CNS lymphoma
- Current Grade greater than (>) 1 toxicity (except alopecia and anorexia) from prior therapy
- Current Grade >1 peripheral neuropathy from any cause
- Glycosylated hemoglobin (HbA1c) >=7.5 percent (%)
- History of severe allergic or anaphylactic reactions to monoclonal antibody therapy (or recombinant antibody-related fusion proteins)
- Prior irradiation to lung fields
- Clinically significant pulmonary disease
- Recent major surgery within 4 weeks prior to Cycle 1, Day 1, other than superficial lymph node biopsies for diagnosis
- Clinically significant history of liver disease, including viral or other hepatitis, current alcohol abuse, or cirrhosis
- Presence of positive test results for hepatitis B (hepatitis B surface antigen [HbsAg] and/or total hepatitis B core antibody [anti-HBc]) or hepatitis C (hepatitis C virus [HCV] antibody)
- Known history of human immunodeficiency virus (HIV) seropositive status
- Women who are pregnant or lactating or intending to become pregnant during the study
- Any abnormal laboratory values as specified in protocol
- Requirement for any excluded medication as specified in protocol
- History of other malignancy that could affect compliance with the protocol or interpretation of results
- 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 render the participant at high risk from treatment complications, including inadequately controlled diabetes or significant cardiovascular 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 intravenous antibiotics or hospitalization (relating to the completion of the course of antibiotics) within 4 weeks prior to Cycle 1, Day 1
- Participants in Phase 1b Stage Only: Vaccination with live vaccines within 6 months before Cycle 1, Day 1