ForPatients
by Roche

Non-Hodgkin's Lymphoma

A study to evaluate the safety, tolerability, processing by the body, mechanism of action, and effectiveness of glofitamab following obinutuzumab pretreatment in patients with B-cell non-Hodgkin lymphoma

A Phase Ib, open-label, dose-escalation, multicenter study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of subcutaneous glofitamab following obinutuzumab pretreatment in patients with relapsed or refractory B-cell non-Hodgkin lymphoma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	7 Countries	BP43015

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

B-cell non-Hodgkin lymphoma (NHL) is a type of cancer where white blood cells called B cells grow abnormally and form tumors throughout the body. The aim of this study is to test the drug glofitamab at different doses to establish the safety and effectiveness of subcutaneous (SC) administration of the drug. SC administration is an injection under the skin of the abdomen in a matter of seconds. Glofitamab has been studied previously as an intravenous (IV) infusion. An IV infusion is a slow injection over several hours into a vein in the arm.

Genentech, Inc (USA)
Sponsor

BP43015
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	>=18 years	No

Who can participate?

Patients aged over 18 years living with relapsed or refractory B#cell non#Hodgkin lymphoma. Relapsed means the cancer has reappeared after a period of remission. Refractory is when the lymphoma does not respond to treatment or when the response to treatment does not last very long.

What does the study involve?
In this study, two drugs will be administered: a pretreatment called obinutuzumab and glofitamab. The pretreatment drug, obinutuzumab, will be administered before the first dose of glofitamab. Obinutuzumab is an antibody that targets the same normal and cancerous cells as glofitamab. Antibodies are a type of blood protein normally made by the immune system to help defend the body against infection and cancer. Obinutuzumab is designed to bind to a protein called CD20 that is present on cancerous B cells, leading to the death of these types of cancer cells. Obinutuzumab has been approved in the United States and Europe for the treatment of B-cell cancers. Obinutuzumab pretreatment will be given as a safety measure to reduce the number of normal and cancerous B cells, mainly in the circulating blood. The reduction of circulating normal and cancerous B cells in advance of receiving the first dose of glofitamab is predicted to reduce any possible side effects that may occur after the first dose of glofitamab. Glofitamab is a new T-cell bispecific antibody with two arms. One arm recognizes a specific protein called CD20 on the surface of B cells, such as cancerous NHL cells. The other arm recognizes T cells, a type of white blood cell that is critical in the body's immune system. By bringing T cells near the cancerous B cells, glofitamab is designed to activate T cells so they can identify and destroy cancer cells. Glofitamab is an experimental drug, which means health authorities have not approved glofitamab in combination with obinutuzumab for the treatment of NHL.

What are the possible benefits and risks of participating?
All patients will be treated with high-quality technical advanced assessments designed by a group of leading experts in the field of cancer therapy. Participant's health may or may not improve in this study, but the information that is learned may help other people who have a similar medical condition in the future. Participants may have side effects from the drugs or procedures used in this study. Side effects can be mild to severe and even life-threatening, and they can vary from person to person. Participants should talk to the study doctor right away if they have any of the following during the study:

- Symptoms that are new or have worsened
- Changes in prescribed or over-the-counter medications (including herbal therapies)
- Visits to the doctor or hospital, including urgent care or emergency room visits

There may be a risk in exposing an unborn child to study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to study drug. Patients who are pregnant, become pregnant, or are currently breastfeeding cannot take part in this study.

Where is the study run from?

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Genentech, Inc (USA)

When is the study starting and how long is it expected to run for?
February 2021 to December 2023

Who is funding the study?
Genentech, Inc (USA)

Who is the main contact? global-roche-genentech-trials@gene.com