ForPatients
by Roche

Non Hodgkin Lymphoma (NHL)

A Dose Escalation Study of RO7082859 as a Single Agent and in Combination With Obinutuzumab, Administered After a Fixed, Single Pre-Treatment Dose of Obinutuzumab in Participants With Relapsed/Refractory B-Cell Non-Hodgkin's Lymphoma

A Dose Escalation Study of Glofitamab (RO7082859) as a Single Agent and in Combination With Obinutuzumab, Administered After a Fixed, Single Pre-treatment Dose of Obinutuzumab in Participants With Relapsed/Refractory B-cell Non-hodgkin's Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	13 Countries	NCT03075696 2016-001185-28,2023-505625-14-00 NP30179

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

Trial Summary:

This is a Phase I/II, multicenter, open-label, dose-escalation study designed to evaluate the efficacy, safety, tolerability and pharmacokinetics (PK) of a novel T-Cell bispecific (TCB), glofitamab, administered by intravenous (IV) infusion as a single agent and in combination with obinutuzumab, following pre-treatment with a one-time, fixed dose of obinutuzumab. This entry-into-human (EIH) study is divided in 3 parts: dose escalation (Parts I and II) and dose expansion (Part III). Single-participant dose-escalation cohorts will be used in Part I, followed by conversion to multiple participant dose-escalation cohorts (Part II), in order to define a tentative maximum tolerated dose (MTD) or optimal biological dose (OBD). The expansion cohorts (Part III) will be initiated when the tentative MTD/OBD is defined, to further evaluate the safety, PK and therapeutic activity of glofitamab.

Hoffmann-La Roche Sponsor	**Phase 1/Phase 2** Phase

NCT03075696 2016-001185-28,2023-505625-14-00 NP30179
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	**>=18 Years**	**No**