ForPatients
by Roche

Non Hodgkin Lymphoma (NHL)

A Study Evaluating the Safety, Efficacy and Pharmacokinetics of Venetoclax Combined With Chemotherapy in Participants With B-Cell Non-Hodgkin's Lymphoma (NHL) and DLBCL

Trial Status	Trial Runs In	Trial Identifier
Completed	10 Countries	NCT02055820 2013-003749-40 GO27878

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 multicenter, open-label, dose-finding study of venetoclax administered orally in combination with rituximab (R) or obinutuzumab (G) and standard doses of cyclophosphamide, doxorubicin, vincristine and oral prednisone (CHOP) in participants with Non-Hodgkin's Lymphoma (NHL). The study consisted of 2 stages: a dose-finding Phase Ib stage and a Phase II expansion stage. In the Phase I portion of the study, participants were randomized to one of 2 treatment arms venetoclax in combination with R-CHOP (Arm A) and venetoclax in combination with G-CHOP (Arm B) and explored the doses of venetoclax in combination with R-CHOP and G-CHOP. The maximum tolerated dose (MTD) of venetoclax in combination with R-CHOP and G-CHOP was determined during the dose-finding stage. For the Phase II portion of the study, the venetoclax dose for venetoclax + R-CHOP was on a non-continuous dosing schedule as determined by the Phase Ib portion of the study based on safety and tolerability observed in participants treated in the dose escalation portion of the study. On 17 July 2016, Roche/Genentech as the sponsor of Study BO21005 (Goya study), a Phase III study that evaluated G CHOP versus R-CHOP in 1L DLBCL, informed through a press release that the primary endpoint of investigator-assessed PFS was not met. Given these results, Arm B (venetoclax + G-CHOP) was not expanded in Phase II in patients who are first-line with DLBCL.

Hoffmann-La Roche
Sponsor

Phase 1/Phase 2
Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	>=18 Years	No