ForPatients
*by Roche*

Non Hodgkin Lymphoma (NHL)Lymphoma

# 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 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 Phase Ib/II, Open-Label Study Evaluating the Safety, Efficacy and Pharmacokinetics of GDC-0199 (ABT-199) in Combination With Rituximab (R) or Obinutuzumab (G) Plus Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) in Patients With B-Cell Non-Hodgkin's Lymphoma (NHL) and DLBCL

## *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 | Phase 1/Phase 2 |
|---|---|
| Sponsor | Phase |

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**NCT02055820 2013-003749-40 GO27878**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| **All** | **#18 Years** | **No** |

## *Inclusion Criteria:*

General Inclusion Criteria:

- At least one bi-dimensionally measurable lymphoma lesion on CT scan defined as > 1.5 cm in its longest dimension, which is also FDG avid by screening PET scan.
- Confirmed availability of archival or freshly biopsied tumor tissue prior to study enrollment
- Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2
- Adequate hematologic function
- For female participants of childbearing potential, agreement to use highly effective forms of contraception

Dose-Escalation Portion of the Study:

- Participants must have histologically confirmed B-cell NHL, except MCL or SLL
- Participants must have never received previous R-CHOP treatment
- Any relapsed/refractory participants that are enrolled during the dose escalation should have received only a single previous treatment regimen

Expansion Portion of the Study:

- Participants must have previously untreated CD20-positive DLBCL and IPI score must be 2-5

## *Exclusion Criteria:*

General Exclusion Criteria:

- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies or known sensitivity or allergy to murine products
- Contraindication to receive any of the individual components of CHOP, rituximab or obinutuzumab
- Prior anthracycline therapy
- Participants with ongoing corticosteroid use >30 mg per day of prednisone or equivalent
- CNS lymphoma or primary mediastinal DLBCL
- Vaccination with live vaccines within 28 days prior to randomization
- Chemotherapy or other investigational therapy within 28 days prior to the start of Cycle 1
- History of other malignancy that could affect compliance with the protocol or interpretation of results
- Evidence of significant, uncontrolled concomitant disease
- Significant cardiovascular disease or significant pulmonary disease
- Left ventricular ejection fraction less than (<) 50% as defined by multiple-gated acquisition (MUGA)

- 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 IV antibiotics or hospitalization (relating to the completion of the course of antibiotics) within 4 weeks prior to Cycle 1 Day 1
- Received the following agents within 7 days prior to the first dose of venetoclax: steroid therapy for anti-neoplastic intent; strong and moderate cytochrome P450 (CYP) 3A4 inhibitors or inducers; grapefruit/ grapefruit products, seville oranges or star fruit within 3 days prior to the first dose of venetoclax
- Clinically significant history of liver disease, including viral or other hepatitis, current alcohol abuse, or cirrhosis
- Recent major surgery
- Women who are pregnant or lactating

## Dose-Escalation Portion of the Study:

- Participants with confirmed mantle cell lymphoma (MCL) or small lymphocytic lymphoma (SLL)

## Expansion Portion of the Study:

- Participants with transformed lymphoma (participants with discordant bone marrow involvement (i.e., low grade histology in bone marrow) may be considered after discussion with the Medical Monitor)
- Prior therapy for NHL