PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

An Open-label, Multi-centre, Randomized, Phase Ib Study to Investigate the Safety and Efficacy of RO5072759 Given in Combination With CHOP, FC or Bendamustine Chemotherapy in Patients With CD20+ B-cell Follicular Non-Hodgkin's Lymphoma

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**This 6 arm study will assess the safety and efficacy of RO5072759 given in combination with
CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), FC (fludarabine,
cyclophosphamide) or bendamustine chemotherapy in patients with CD20+ B-cell follicular
non-Hodgkin's lymphoma. Patients with relapsed or refractory disease will be assigned by
physician choice to either the CHOP treatment arm, to receive a maximum of 8x3weekly cycles
of treatment, or the FC treatment arm, to receive a maximum of 6x4weekly cycles of
treatment, and will then be randomized to receive combination treatment with RO5072759
either at a dose of 400 mg iv for all infusions, or at a dose of 1600 mg iv for the first 2
infusions, followed by 800 mg for all subsequent infusions. Previously untreated patients
will receive first-line treatment with RO5072759 at a dose of 1000 mg for either a maximum
of 8x3 weekly cycles in combination with CHOP or for a maximum of 6x4 weekly cycles in
combination with bendamustine. The anticipated time on study treatment is 3-27 months.

Patients with complete response or partial response after first line RO5072759 +
chemotherapy may receive maintenance treatment with RO5072759 every 3 months for 2 years or
until disease progression, whichever comes first.**

Brief Summary in Scientific Language

[---]*

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003833**
- Date of Registration in DRKS: **2012/05/04**
- Date of Registration in Partner Registry or other Primary Registry: **2009/01/16**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2008-001643-19**
- Primary Registry-ID: **NCT00825149 (ClinicalTrials.gov)**
- Sponsor-ID: **BO21000 (Hoffmann-La Roche)**
- Other Secondary-ID: **2008-001643-19**

Health condition or Problem studied

- Free text: **Non-Hodgkin's Lymphoma**
- ICD10: **C83.3 - Non-Hodgkin's lymphoma: Large cell (diffuse)**

Interventions/Observational Groups

- Arm 1: **Drug: RO5072759**
- Arm 2: **Drug: RO5072759**
- Arm 3: **Drug: CHOP(cyclophosphamide,doxorubicin,vincristine,prednisone)**
-

Arm 4: **Drug: FC(fludarabine,cyclophosphamide)**

- Arm 5: **Drug: RO5072759**
- Arm 6: **Drug: bendamustine**
- Arm 7: **Drug: RO5072759**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **I**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Safety: Incidence of adverse events; time frame: up to 6 years

Secondary Outcome

- Overall response rate :assessments according to the Criteria for evaluation of response in Non-Hodgkin's Lymphoma (International Workshop to Standardize Response criteria for NHL); time frame: 12 weeks
- Complete response rate: assessments according to the Criteria for evaluation of response in Non-Hodgkin's Lymphoma (International Workshop to Standardize Response criteria for NHL); time frame: 12 weeks
- Progression- and event-free survival; time frame: up to 6 years
- Pharmacokinetics of RO5072759 (AUC, Cmax, CL); time frame: 26 weeks
- Pharmacodynamics: peripheral blood B-cell depletion and recovery; time frame: up to 27 months

Countries of recruitment

- AU **Australia**
- FR **France**
- DE **Germany**
-

IT **Italy**

- ES **Spain**
- UK **United Kingdom**

Locations of Recruitment

- **Aschaffenburg**
- **Freiburg**
- **Göttingen**
- **Heidelberg**
- **Kiel**
- **Köln**
- **Muenchen**
- **Ulm**
- **Wuerzburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2009/02/27**
- Target Sample Size: **136**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Adult patients, >18 years of age

- Either CD20+ relapsed or refractory B-cell follicular non-Hodgkin's lymphoma (after a maximum of 2 prior chemotherapy regimens) or CD20+ B-cell follicular non-Hodgkin's lymphoma with no prior systemic therapy

- ECOG performance status of 0-2

Exclusion criteria

- Prior administration of rituximab within 8 weeks of study entry, or 3 months for any radioimmunotherapy

- Central nervous lymphoma

- History of other malignancies within 2 years of study entry which could affect compliance with the protocol or interpretation of results

- Active infection, or any major episode of infection requiring hospitalization or treatment with iv antibiotics within 4 weeks of dosing

Addresses

- **Primary Sponsor**

  Hoffmann-La Roche

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

  Hoffmann-La Roche
  Clinical Trials

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Public Queries**

  Reference Study ID Number: BO21000
  www.roche.com/about_roche/roche_worldwide.htm

  Telephone: **888-662-6728 (U.S. Only)**
  Fax: **[---]***
  E-mail: **global.rochegenentechtrials at roche.com**
  URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 123
- Last processed date by ClinicalTrials.gov: 2013/10/30

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*