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

Trial Description

Title

A MULTICENTER, PHASE III, OPEN-LABEL, RANDOMIZED STUDY IN RELAPSED/REFRACTORY PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA TO EVALUATE THE BENEFIT OF GDC-0199 (ABT-199) PLUS RITUXIMAB COMPARED WITH BENDAMUSTINE PLUS RITUXIMAB

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This open-label, randomized study will compare the efficacy of GDC-0199 plus rituximab (GDC-0199+R) with bendamustine plus MabThera/Rituxan (Rituximab) (B+R) in patients with relapsed or resistant chronic lymphocytic leukemia. Patients will be randomized 1:1 into the two arms. Patients randomized to GDC-0199+R will be given GDC-0199 daily (oral, target dose 400 mg) and will receive 6 cycles of rituximab infused intravenously (IV) on Day 1 of each 28-day cycle (Cycle 1: 375 mg/m2; Cycles 2-6: 500 mg/m2).

Patients randomized to B+R will receive 6 cycles of treatment consisting of a rituximab infusion (Cycle 1: 375 mg/m2; Cycles 2-6: 500 mg/m2) on Day 1 and bendamustine infusions (70 mg/m2) on Days 1 and 2 of each 28-day cycle.

Patients in the GDC-0199+R arm will continue GDC-0199 treatment until disease progression or 2 years since treatment start, whichever comes first. Anticipated time on study is up to 5 years.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00006063**
- Date of Registration in DRKS: **2014/04/29**
- Date of Registration in Partner Registry or other Primary Registry: **2013/12/04**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02005471 (ClinicalTrials.gov)**
- Sponsor-ID: **GO28667 (Hoffmann-La Roche)**

Health condition or Problem studied

- Free text: **Chronic Lymphocytic Leukemia**
- ICD10: **C91.1 - Chronic lymphocytic leukaemia of B-cell type**

Interventions/Observational Groups

- Arm 1: **Drug: GDC-0199**
- Arm 2: **Drug: Rituximab [MabThera/Rituxan]**
- Arm 3: **Drug: Bendamustine**

Characteristics

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

Primary Outcome

- Investigator-assessed progression-free survival (PFS), defined as time from randomization until disease progression or death from any cause.; time frame: Up to 5 years

Secondary Outcome

- Overall response rates; time frame: Assessed 2-3 months after end of treatment
- Incidence of adverse events; time frame: Up to 5 years
- Patient-reported outcome measure; time frame: Up to 5 years

Countries of recruitment

- US **United States**
- AU **Australia**
- AT **Austria**
- BE **Belgium**
- CA **Canada**
- CZ **Czech Republic**
- DK **Denmark**
- FR **France**
- DE **Germany**
- HU **Hungary**
- IT **Italy**
- KR **Korea, Republic of**
- NL **Netherlands**
- NZ **New Zealand**
- PL **Poland**
- ES **Spain**
- SE **Sweden**
- CH **Switzerland**
- TW **Taiwan, Province of China**
- UK **United Kingdom**

Locations of Recruitment

- **Berlin**
- **Berlin**
- **Dresden**
- **Freiburg**
- **Heidelberg**
- **Kiel**
- **Koeln**
- **Moenchengladbach**
- **Muenchen**
- **Muenchen**
- **München**
- **München**
- **Tuebingen**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2013/12/31**
- Target Sample Size: **370**
- 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

- Age > / = 18 years.

- Diagnosis of chronic lymphocytic leukemia (CLL) per diagnostic criteria and relapsed or refractory CLL per the iwCLL guidelines.

- Previously treated with 1-3 lines of therapy (e.g. completed > / = two treatment cycles per therapy), including at least one standard chemotherapy-containing regimen.

- Patients previously treated with bendamustine only if their duration of

response was
> / = 24 months.

- Eastern Cooperative Oncology Group (ECOG) performance score of < / = 1.

- Adequate bone marrow function.

- Adequate renal and hepatic function.

- Patients must use effective birth control throughout study until 1 year after
rituximab treatment; female patients must not be pregnant or breast-feeding.

Exclusion criteria

- Transformation of CLL to aggressive non-Hodgkin lymphoma or CNS involvement by CLL.

- Undergone an allogenic stem cell transplant.

- A history of significant renal, neurologic, psychiatric, endocrine, metabolic,
immunologic, cardiovascular or hepatic disease.

- Hepatitis B or C or known HIV positive.

- Receiving warfarin treatment.

- Received an anti-CLL monoclonal antibody within 8 weeks prior to the first dose of
study drug.

- Received any anti-cancer or investigational therapy within 14 days prior to the first
dose of study drug or has not recovered from previous therapy.

- Received CYP3A4 inhibitors (such as fluconazole, ketoconazole and clarithromycin) or
inducers (such as rifampin, carbamezapine, phenytoin, St. John's Wort) within 7 days
prior to the first dose of GDC-0199.

- Prior GDC-0199 treatment.

- Patients with another cancer, history of another cancer considered uncured on in
complete remission for < 5 years, or currently under treatment for another suspected
cancer except non-melanoma skin cancer or carcinoma in situ of the cervix that has
been treated or excised and is considered resolved.

- Malabsorption syndrome or other condition that precludes enteral route of administration.

- Other clinically significant uncontrolled condition(s) including, but not limited to,
systemic infection (viral, bacterial or fungal).

- Vaccination with a live vaccine within 28 days prior to randomization.

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: GO28667
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: **[---]***

[---]*

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: 84
- Last processed date by ClinicalTrials.gov: 2014/04/01

** 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.*