Trial record **1 of 1** for: CAMN107ADE20 NiloDeepR

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Study Assessing Deep Molecular Response in Adult Patients With CML in Chronic Phase Treated With Nilotinib Firstline. (NILOdeepR)

This study is currently recruiting participants.

See Contacts and Locations

Verified November 2017 by Novartis (Novartis Pharmaceuticals)

Sponsor:
Novartis Pharmaceuticals

ClinicalTrials.gov Identifier:
NCT02546674

First Posted: September 11, 2015
Last Update Posted: November 14, 2017

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

Full Text View | Tabular View | No Study Results Posted | Disclaimer

How to Read a Study Record

Purpose

The main purpose of this study is evaluation of deep molecular response (MR4.5; BCR-ABL IS < 0.0032%) after 24 months of therapy with nilotinib in newly diagnosed patients with chronic phase CML. Via the use of MR4.5 EUTOS ('European Treatment and Outcome Study for CML') laboratories adequate and reliable molecular monitoring as a key parameter for assessing molecular milestones is fostered. Furthermore this trial aims to investigate early prediction of outcome in newly diagnosed patients with nilotinib by assessing the individual decline of BCR-ABL transcripts. Quality of life will bemeasured via use of the EORTC CML-24 questionnaire.

Condition	Intervention	Phase
Chronic Myeloid Leukemia	Drug: Nilotinib	Phase 4

Study Type: Interventional

Study Design: Intervention Model: Single Group Assignment
Masking: None (Open Label)
Primary Purpose: Treatment

Official Title: A Phase IV Single Arm, Multicenter, Open-label Study Assessing Deep Molecular Response in Adult Patients With Newly Diagnosed Philadelphia Chromosome Positive CML in Chronic Phase After Two Years of Treatment With Nilotinib 300mg BID

Resource links provided by NLM:

Genetics Home Reference related topics: chronic myeloid leukemia

Drug Information available for: Nilotinib

Genetic and Rare Diseases Information Center resources: Myeloid Leukemia Chronic Myeloid Leukemia Chronic Myeloproliferative Disorders

U.S. FDA Resources

Further study details as provided by Novartis (Novartis Pharmaceuticals):

Primary Outcome Measures:

- Proportion of patients that achieve deep molecular response MR4.5 (IS) at 24 months of study treatment, measured in a standardized EUTOS MR4.5 laboratory [Time Frame: 24 months]

The primary efficacy variable is the rate of MR4.5 at 24 months of study treatment measured in a standardized EUTOS MR4.5 laboratory. The rate of MR4.5 (IS) at 24 months of study treatment will be computed by dividing the number of patients who fit the definition of response at 24 months by the total number of patients in the analysis set.

Secondary Outcome Measures:

- Proportion of patients with MMR at 12 months of study treatment [Time Frame: 12 months]

  The rate of MMR at 12 months of study treatment will be computed by dividing the number of patients who fit the definition of response at 12 months by the total number of patients in the analysis set

- Proportion of patients with CCyR at 6 months of study treatment [Time Frame: 6 months]

  Rate of CCyR at 6 months of study treatment will be calculated by dividing the number of patients who fit the definition of response at 6 month by the total number of Ph+ patients in the analysis set

- Progression-free survival [Time Frame: up to 24 months]

  Progression-free survival is defined as the time from the date of start of study treatment to the date of event defined as the first documented disease progression to AP/BC or the date of death from any cause, whichever is earlier

- Proportion of patients with MR4 at 24 months of study treatment [Time Frame: 24 months]

  The rate of MR4 (IS) at 24 months of study treatment will be computed by dividing the number of patients who fit the definition of response at 24 months by the total number of patients in the analysis set

- Individual reduction of BCR-ABL transcripts [Time Frame: 3 months]

  For determination of actual individual decline of transcripts a ratio will be established given by BCR-ABL/GUS at 3 months divided by BCR-ABL/GUS at diagnosis and referred to as 3-month reduction ratio.

Estimated Enrollment:	171
Actual Study Start Date:	February 18, 2016
Estimated Study Completion Date:	February 18, 2020
Estimated Primary Completion Date:	

February 18, 2020 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Nilotinib Patients with newly diagnosed CML in chronic phase will be enrolled.	Drug: Nilotinib Nilotinib will be prescribed by the investigator according to the patient's medical need.

Eligibility

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patients with newly diagnosed (within 6 months) Philadelphia chromosome positive CML in chronic phase; Patients must be previously untreated for CML with the exception of 6 months treatment with hydroxyurea and a maximum of 6 weeks treatment with imatinib

Exclusion Criteria:

-Known impaired cardiac function like long QT syndrome, history of myocardial infarction or unstable angina in the past 12 months. Patients who are pregnant or breast feeding.

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02546674***

Contacts

Contact: Novartis Pharmaceuticals +41613241111 Novartis.email@novartis.com

Contact: Novartis Pharmaceuticals

Show 70 Study Locations

Sponsors and Collaborators

Novartis Pharmaceuticals

More Information

Additional Information:

Related Info EXIT

Responsible Party:	Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT02546674 History of Changes
Other Study ID Numbers:	**CAMN107ADE20**
First Submitted:	September 9, 2015
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Last Verified:	November 2017

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Novartis (Novartis Pharmaceuticals):
Chronic Myeloid Leukemia
Nilotinib
Molecular Response
MR4.5

Additional relevant MeSH terms:

Leukemia, Myeloid

Leukemia, Myelogenous, Chronic, BCR-ABL Positive

Leukemia

Neoplasms by Histologic Type

Neoplasms

Myeloproliferative Disorders

Bone Marrow Diseases

Hematologic Diseases