Safety And Efficacy Study Of Bosutinib In Patients With Philadelphia Chromosome Positive Chronic Myeloid Leukemia Previously Treated With One Or More Tyrosine Kinase Inhibitors

This study is currently recruiting participants. (see Contacts and Locations)

Verified August 2015 by Pfizer

Sponsor:
Pfizer

Collaborator:
Developmental Therapeutics Consortium

Information provided by (Responsible Party):
Pfizer

ClinicalTrials.gov Identifier:
NCT02228382

First received: August 27, 2014
Last updated: August 17, 2015
Last verified: August 2015
History of Changes

Purpose

The purpose of this study is to fulfill the post-authorization commitment made by Pfizer to the European Medicines Agency in providing additional safety and efficacy data in approximately 150 Philadelphia Chromosome Positive Chronic Myeloid Leukemia patients with high unmet medical need, including 75 Chronic Phase, Accelerated Phase or Blast Phase patients in the fourth or later line treatment setting (i.e., after treatment with at least 3 other Tyrosine Kinase Inhibitors).

Condition	Intervention	Phase
Previously Treated PH + CML	Drug: Bosutinib	Phase 4

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase 4 Safety And Efficacy Study Of Bosutinib (Bosulif (Registered)) In Patients With Philadelphia Chromosome Positive Chronic Myeloid Leukemia Previously Treated With One Or More Tyrosine Kinase Inhibitors

Resource links provided by NLM:

Genetics Home Reference related topics: tetrasomy 18p

MedlinePlus related topics: Chronic Myeloid Leukemia Leukemia

Drug Information available for: Bosutinib

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

U.S. FDA Resources

Further study details as provided by Pfizer:

Primary Outcome Measures:

- Percentage of Participants with Major Cytogenetic Response (MCyR) by Week 52 in Chronic Phase Second-line Population and Chronic

Phase Third-line Population of Philadelphia Chromosome Positive Chronic Myeloid Leukemia patients. [Time Frame: Week 52]
[Designated as safety issue: No]

Cytogenetic response (CyR) is based on the prevalence of Philadelphia positive cells in metaphase from Bone Marrow sample.

- Percentage of Participants w ith Major Cytogenetic Response (MCyR) by Week 52 in Chronic Phase Fourth-line and later-line Population of Philadelphia Chromosome Positive Chronic Myeloid Leukemia patients. [Time Frame: Week 52] [Designated as safety issue: No]

  Cytogenetic response (CyR) is based on the prevalence of Philadelphia positive cells in metaphase from Bone Marrow sample.

- Percentage of Participants w ith Overall Hematologic Response (OHR) by Week 52 in Advanced Leukemia Population patients.
  [Time Frame: Week 52] [Designated as safety issue: No]

  OHR includes Complete Hematological Response (CHR) or return to chronic phase (RCP).

Secondary Outcome Measures:

- Estimate cumulative probability of Percentage of Participants w ith Major Cytogenetic Response in Chronic Phase and Advanced Phase Philadelphia Chromosome Positive Chronic Myeloid Leukemia patient populations. [Time Frame: Week 52]
  [Designated as safety issue: No]

  Cytogenetic response (CyR) is based on the prevalence of Philadelphia positive cells in metaphase from Bone Marrow sample.

- Estimate cumulative probability of Percentage of Participants w ith Overall Hematologic Response in the Accelerated Phase and Blast Phase Philadelphia Chromosome Positive Chronic Myeloid Leukemia patient population by number of lines of prior therapy. [Time Frame: Week 52]
  [Designated as safety issue: No]

  OHR includes Complete Hematological Response (CHR) or return to chronic phase (RCP).

- Characterize distribution of best response (molecular, cytogenetic, or hematologic) in the Chronic Phase, Accelerated Phase and Blast Phase Philadelphia Chromosome Positive Chronic Myeloid Leukemia patient populations. [Time Frame: Week 52]
  [Designated as safety issue: No]
- Estimating probability of Percentage of Participants w ith Major Cytogenetic Response at 3, 6, 12, 18, and 24 months in the Chronic Phase, Accelerated Phase and Blast Phase Philadelphia Chromosome Positive Chronic Myeloid Leukemia patient populations. [Time Frame: Month 3, 6, 12, 18, and 24] [Designated as safety issue: No]
- Estimating the probability of confirmed Overall Hematologic Response at 3, 6, 9, 12, 18, and 24 months in the Accelerated Phase and Blast Phase Philadelphia Chromosome Positive Chronic Myeloid Leukemia patient populations. [Time Frame: Month 3, 6, 9, 12, 18, and 24]
  [Designated as safety issue: No]
- Estimating the probability of cumulative confirmed Complete Hematologic Response in the Chronic Phase, Accelerated Phase and Blast Phase Philadelphia Chromosome Positive Chronic Myeloid Leukemia patient populations. [Time Frame: Week 52]
  [Designated as safety issue: No]
- Estimating the probability of cumulative major molecular response in the Chronic Phase, Accelerated Phase and Blast Phase Philadelphia Chromosome Positive Chronic Myeloid Leukemia patient populations. [Time Frame: Week 52] [Designated as safety issue: No]

Estimated Enrollment:	165
Study Start Date:	November 2014
Estimated Study Completion Date:	July 2021
Estimated Primary Completion Date:	July 2021 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Bosutinib	Drug: Bosutinib 100 mg and 500 mg tablets, once daily dosage up to 4 years duration Other Name: BOSULIF

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria
Inclusion Criteria:

- Confirmed Philadelphia Chromosome positive Chronic Myeloid Leukemia or Confirmed BCR-ABL1 (Abelson-break point cluster) Positive if Philadelphia Chromosome negative Chronic Myeloid Leukemia (from initial diagnosis).
- Prior treatment with 1 or more tyrosine kinase inhibitor drugs (imatinib, dasatinib and/or nilotinib) for Philadelphia Chromosome positive Chronic Myeloid Leukemia (CML).
- Any Chronic Myeloid Leukemia disease phase, as long as the patient is unable to receive treatment with imatinib, dasatinib and/or nilotinib for any reason.

Exclusion Criteria:

- Participation in any other clinical studies involving investigational drug(s) within 14 days or within 3 half-lives of drug levels in blood (whichever is longer) prior to the first dose of bosutinib.
- Prior treatment with bosutinib.
- Prior treatment with ponatinib.
- Known T315I or V299L mutation.

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02228382

Contacts

Contact: Pfizer CT.gov Call Center 1-800-718-1021

Show 53 Study Locations

Sponsors and Collaborators

Pfizer

Developmental Therapeutics Consortium

Investigators

Study Director: Pfizer CT.gov Call Center Pfizer

More Information

Additional Information:

To obtain contact information for a study center near you, click here.

No publications provided

Responsible Party:	Pfizer
ClinicalTrials.gov Identifier:	NCT02228382 History of Changes
Other Study ID Numbers:	**B1871039**, 2013-003250-25
Study First Received:	August 27, 2014
Last Updated:	August 17, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Pfizer:

Bosutinib
Chronic Myeloid Leukemia
CML
Leukemia
Myelogenous
Chronic
BC-ABL Positive

Additional relevant MeSH terms:

Abnormal Karyotype
Leukemia, Myelogenous, Chronic, BCR-ABL Positive
Leukemia, Myeloid
Philadelphia Chromosome
Bone Marrow Diseases
Chromosome Aberrations
Leukemia
Myeloproliferative Disorders
Neoplasms
Neoplasms by Histologic Type
Pathologic Processes
Translocation, Genetic

Hematologic Diseases

ClinicalTrials.gov processed this record on September 03, 2015