Trial record **1 of 1** for: BAY 1436032 / 19036

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BAY1436032 in Patients With Mutant IDH1(mIDH1) Advanced Acute Myeloid Leukemia (AML)

ClinicalTrials.gov Identifier: NCT03127735

Recruitment Status : Recruiting
First Posted : April 25, 2017
Last Update Posted : December 21, 2017

See **Contacts and Locations**

Sponsor:
Bayer

Information provided by (Responsible Party):
Bayer

Study Details | **Tabular View** | **No Results Posted** | Disclaimer

How to Read a Study Record

Study Description

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Brief Summary:

To determine the maximum tolerated and / or recommended Phase II dose of oral mutant IDH1 (mIDH1) inhibitor **BAY1436032** and to characterize its safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary clinical efficacy in patients with mIDH1-R132X advanced acute myeloid leukemia (AML)

Condition or disease	Intervention/treatment	Phase
Leukemia, Myeloid, Acute	Drug: **BAY1436032**	Phase 1

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	80 participants
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	An Open-label, Non-randomized, Multicenter Phase I Study to Determine the Maximum Tolerated and / or Recommended Phase II Dose of Oral Mutant IDH1 (mIDH1) Inhibitor **BAY1436032** and to Characterize Its Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Clinical Efficacy in Patients With mIDH1-R132X Advanced Acute Myeloid Leukemia (AML)
Actual Study Start Date :	June 14, 2017
Estimated Primary Completion Date :	August 31, 2019
Estimated Study Completion Date :	October 11, 2019

Resource links provided by the National Library of Medicine

Genetics Home Reference related topics:

Core binding factor acute myeloid leukemia

Cytogenetically normal acute myeloid leukemia

Familial acute myeloid leukemia with mutated CEBPA

MedlinePlus related topics: Acute Myeloid Leukemia

Leukemia

Genetic and Rare Diseases Information Center
resources: Myeloid Leukemia
Acute Myeloid Leukemia
Acute Non Lymphoblastic Leukemia

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: **BAY1436032** Dose escalation: Various doses of study drug will be tested on a small number of patients/dose with the goal of identifying the most appropriate dose(s) for further evaluation in dose expansion. The MTD of the study drug may or may not be identified. It is anticipated that 3-4 patients will be treated at each dose of study drug to be tested and that 15-20 total patients will be treated in this part of the trial. Dose expansion: Up to 2 different doses of study drug will be tested on up to 30 patients/dose with the goal of identifying the most appropriate RP2D for further clinical development. The doses to be evaluated in this part of the trial will be selected based on information obtained during dose escalation.	Drug: **BAY1436032** **BAY1436032** administered continuously as a single agent dosed twice a day orally on Days 1 to 28 of a 28-day cycle. Patients may continue treatment with **BAY1436032** until disease progression, development of other unacceptable toxicity or Investigator discretion.

Outcome Measures

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Primary Outcome Measures :

1. Maximum tolerated dose (MTD) or RP2D of **BAY1436032** [Time Frame: Within first 4 weeks of first dose]

   If the MTD is not reached during dose escalation, the primary variable will be the recommended phase 2 dose (RP2D) of BAY1436032

2. Number of participants with Adverse Events as a Measure of [Time Frame: Up to 12 weeks]

   As a measure of safety and tolerability

Secondary Outcome Measures :

1. Objective efficacy response [Time Frame: Up to 12 weeks]

   Response assessment for AML in this study will be based on the modified Cheson criteria. The following categories are used to capture the investigator's AML response evaluation:

   - Complete remission (CR)
   - morphologic CR with incomplete blood count recovery (CRi)
   - partial remission (PR)
   - No response - treatment failure

2. Duration of response [Time Frame: Up to 12 weeks]

   Efficacy data

3. Event-free survival (EFS) [Time Frame: Up to 12 weeks]

   EFS defined as time from start of treatment to treatment failure, relapse, or death due to any cause.

4. Change of 2 hydroxyglutarate (2-HG) level obtained at baseline and post-baseline [Time Frame: Up to 12 weeks]

   Assess pharmacodynamic (PD) effects and evidence of clinical efficacy associated with BAY 1436032 administration in patients. Change from baseline and percent change from baseline will be calculated.

5. Cmax (maximum observed drug concentration in plasma after a single dose) [Time Frame: Cycle 1 Day 1: Pre-dose, 0.5, 1, 2, 3, 4, 6, 8, 12, 24 hour post-dose (each cycle is 28 days)]

   As a secondary objective of this study evaluate the pharmacokinetics (PK) of BAY 1436032 in patients.

   PK parameters normalized for dose and / or dose and body weight will be calculated.

6. AUC(0-8) (AUC from time 0 to 8 h after a single dose) [Time Frame: Cycle 1 Day 1: Pre-dose, 0.5, 1, 2, 3, 4, 6, and 8 hour post-dose (each cycle is 28 days)]

   As a secondary objective of this study evaluate the pharmacokinetics (PK) of BAY 1436032 in patients.

   PK parameters normalized for dose and / or dose and body weight will be calculated.

7. AUC(0-12) (AUC from time 0 to 12 h after a single dose) [Time Frame: Cycle 1 Day 1: Pre-dose, 0.5, 1, 2, 3, 4, 6, 8, 12 hour post-dose (each cycle is 28 days)]

   if feasible

8. Cmax,md (Cmax after multiple doses) [Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 6, 8, and 12 hour post-dose on Day 15; (each cycle is 28 days)]

   As a secondary objective of this study evaluate the pharmacokinetics (PK) of BAY 1436032 in patients.

   PK parameters normalized for dose and / or dose and body weight will be calculated.

9. AUC(0-8)md (AUC from time 0 to 8 h after multiple doses) [Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 6, and 8 hour post-dose on Day 15; (each cycle is 28 days)]

   As a secondary objective of this study evaluate the pharmacokinetics (PK) of BAY 1436032 in patients.

   PK parameters normalized for dose and / or dose and body weight will be calculated.

10. AUC(0-12)md (AUC from time 0 to 12 h after multiple doses) [Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 6, and 8 hour post-dose on Day 15; (each cycle is 28 days)]

    if feasible

Eligibility Criteria

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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 advanced AML that harbors IDH1 mutation
- Patients are relapsed from or refractory to at least 1 previous line of therapy
- Good kidney and liver function
- Male or female patients
- Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2
- Women must have a negative serum pregnancy test within 7 days prior to the first dose of study drug or be surgically or biologically sterile or postmenopausal

Exclusion Criteria:

- Previously treated with any prior mIDH1 targeted therapy
- Extramedullary disease only
- History of clinically significant or active cardiac disease
- Active clinically significant infection
- Unresolved chronic toxicity of previous AML treatment
- Taking known strong cytochrome P450 (CYP) 2C8 inducers or inhibitors
- Pregnancy or breast-feeding

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

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): ***NCT03127735***

Contacts

Contact: Bayer Clinical Trials Contact	(+) 1-888-8422937 clin
Contact: For trial location information (Phone Menu Options '3' or '4')	(+)1-888-84 22937

Locations

United States, California

University of Southern California Keck School of Medicine Los Angeles, California, United States, 90033-9172	**Not yet recruiting**

United States, Florida

University of Florida-Gainesville Gainesville, Florida, United States, 32608	**Not yet recruiting**

United States, Georgia

Northside Hospital - Atlanta Atlanta, Georgia, United States, 30342	**Not yet recruiting**

United States, Illinois

Northwestern Memorial Hospital Chicago, Illinois, United States, 60611-2908	**Not yet recruiting**
University of Chicago Chicago, Illinois, United States, 60637	**Not yet recruiting**

United States, New York

Montefiore Medical Center Bronx, New York, United States, 10467-2490	**Recruiting**
Roswell Park Cancer Institute Buffalo, New York, United States, 14263-0001	**Not yet recruiting**
Mount Sinai Medical Center New York, New York, United States, 10029	**Recruiting**

United States, North Carolina

Wake Forest Baptist Health Winston-Salem, North Carolina, United States, 27157	**Not yet recruiting**

United States, Ohio

Ohio State University — **Recruiting**
Columbus, Ohio, United States, 43210

United States, Pennsylvania

University of Pennsylvania — **Not yet recruiting**
Philadelphia, Pennsylvania, United States, 19104

Thomas Jefferson University — **Recruiting**
Philadelphia, Pennsylvania, United States, 19107

United States, Texas

University of Texas MD Anderson Cancer Center — **Not yet recruiting**
Houston, Texas, United States, 77030

Germany

Universitätsklinikum Heidelberg — **Not yet recruiting**
Heidelberg, Baden-Württemberg, Germany, 69120

Klinikum rechts der Isar — **Not yet recruiting**
München, Bayern, Germany, 81675

Medizinische Hochschule Hannover (MHH) — **Not yet recruiting**
Hannover, Niedersachsen, Germany, 30625

Universitätsklinikum Essen — **Not yet recruiting**
Essen, Nordrhein-Westfalen, Germany, 45122

Universitätsklinikum Leipzig AöR — **Not yet recruiting**
Leipzig, Sachsen, Germany

Universitätsklinikum Charite zu Berlin — **Not yet recruiting**
Berlin, Germany, 12200

Universitätsklinikum Hamburg Eppendorf (UKE) — **Not yet recruiting**
Hamburg, Germany, 20246

Sponsors and Collaborators

Bayer

More Information

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Responsible Party: Bayer
ClinicalTrials.gov Identifier: NCT03127735 History of Changes
Other Study ID Numbers: **19036**
2016-004095-22 (EudraCT Number)

First Posted:	April 25, 2017 Key Record Dates
Last Update Posted:	December 21, 2017
Last Verified:	December 2017

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

Keywords provided by Bayer:
Phase 1
mIDH1
IDH1 mutation
mIDH1 inhibitor

Additional relevant MeSH terms:
Leukemia
Leukemia, Myeloid
Leukemia, Myeloid, Acute
Neoplasms by Histologic Type
Neoplasms