Trial record **1 of 1** for: AC220-A-U302

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Quizartinib With Standard of Care Chemotherapy and as Maintenance Therapy in Patients With Newly Diagnosed FLT3-ITD (+) Acute Myeloid Leukemia (AML) (QuANTUM-First)

ClinicalTrials.gov Identifier: NCT02668653

Recruitment Status : Recruiting
First Posted : January 29, 2016
Last Update Posted : December 5, 2017

See **Contacts and Locations**

Sponsor:
Daiichi Sankyo, Inc.

Information provided by (Responsible Party):
Daiichi Sankyo, Inc.

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

How to Read a Study Record

Study Description

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Brief Summary:

This is a phase 3, randomized, double-blind, placebo-control global study. The purpose of this study is to compare the effect of quizartinib versus placebo (administered with standard induction and consolidation chemotherapy, then administered as maintenance therapy for up to 12 cycles) on event-free survival in subjects with FLT3-internal tandem duplication (ITD) positive AML.

Condition or disease	Intervention/treatment	Phase
Acute Myeloid Leukemia Leukemia	Drug: Chemotherapy Drug: Quizartinib Drug: Placebo	Phase 3

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	536 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Triple (Participant, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	A Phase 3, Double-Blind, Placebo-controlled Study of Quizartinib Administered in Combination With Induction and Consolidation Chemotherapy, and Administered as Maintenance Therapy in Subjects 18 to 75 Years Old With Newly Diagnosed FLT3-ITD (+) Acute Myeloid Leukemia
Actual Study Start Date :	September 2016
Estimated Primary Completion Date :	November 2020
Estimated Study Completion Date :	November 2020

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
Soft Tissue Sarcoma

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Chemotherapy plus quizartinib Induction: up to 2 cycles with cytarabine and daunorubicin/idarubicin, followed by the experimental drug quizartinib Consolidation: up to 4 cycles of cytarabine followed by the experimental drug quizartinib and/or hematopoeitic stem cell transplant Maintenance: up to 12 cycles with the experimental drug quizartinib	Drug: Chemotherapy Other Names: • Cytarabine • Daunorubicin • Idarubicin Drug: Quizartinib Other Name: Test Product
Active Comparator: Chemotherapy plus placebo Induction: up to 2 cycles with cytarabine and daunorubicin/idarubicin, followed by placebo Consolidation: up to 4 cycles of cytarabine followed by placebo and/or hematopoeitic stem cell transplant Maintenance: up to 12 cycles with placebo	Drug: Chemotherapy Other Names: • Cytarabine • Daunorubicin • Idarubicin Drug: Placebo Other Name: Placebo Control

Outcome Measures

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Primary Outcome Measures :

1. Event-free Survival (EFS) [Time Frame: Duration of study, an average of 2 years]

Secondary Outcome Measures :

1. Overall survival [Time Frame: Duration of study, an average 2 years]
2. Complete remission (CR) rate at the end of the first Induction cycle
   [Time Frame: Approximately 42 days]
3. Composite CR rate at the end of the first Induction cycle [Time Frame: Approximately 42 days]
4. Percentage of participants achieving CR with no evidence of minimal residual disease
   [Time Frame: Approximately 42 days]

Eligibility Criteria

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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 to 75 Years (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Must be competent and able to comprehend, sign, and date an Ethics Committee (EC) or Institutional Review Board approved Informed Consent Form (ICF) before performance of any study-specific procedures or tests;
2. Is ≥18 years or the minimum legal adult age (whichever is greater) and ≤75 years (at Screening);

3. Newly diagnosed, morphologically documented primary AML or AML secondary to myelodysplastic syndrome or a myeloproliferative neoplasm, based on the World Health Organization (WHO) 2008 classification (at Screening);
4. Eastern Cooperative Oncology Group (ECOG) performance status 0-2 (at the time the subject signs their first informed consent form);
5. Presence of FLT3-ITD activating mutation in bone marrow (allelic ratio of ≥3% FLT3-ITD/total FLT3);
6. Participant is receiving standard "7+3" induction chemotherapy regimen as specified in the protocol;
7. Adequate renal function defined as:

   a. Creatinine clearance >50 mL/min, as calculated with the modified Cockcroft Gault equation
8. Adequate hepatic function defined as:
    1. Total serum bilirubin (TBL) ≤1.5 × upper limit of normal (ULN);
    2. Serum alkaline phosphatase, aspartate transaminase (AST) and alanine transaminase (ALT) ≤2.5 × ULN;
9. Serum electrolytes within normal limits: potassium, calcium (total, or corrected for serum albumin in case of hypoalbuminemia) and magnesium. If outside of normal limits, subject will be eligible when electrolytes are corrected;
10. If a woman of childbearing potential, must have a negative serum pregnancy test upon entry into this study and must be willing to use highly effective birth control upon enrollment, during the treatment period and for 6 months following the last dose of investigational drug or cytarabine, whichever is later. A woman is considered of childbearing potential following menarche and until becoming postmenopausal (no menstrual period for a minimum of 12 months);
11. If male, must be surgically sterile or willing to use highly effective birth control upon enrollment, during the treatment period, and for 6 months following the last dose of investigational drug or cytarabine, whichever is later.

Exclusion Criteria:

1. Diagnosis of acute promyelocytic leukemia (APL), French-American-British classification M3 or WHO classification of APL with translocation, t(15;17)(q22;q12), or breakpoint cluster region-Abelson murine leukemia viral oncogene homolog 1 (BCR-ABL) positive leukemia (ie, chronic myelogenous leukemia in blast crisis); subjects who undergo diagnostic workup for APL and treatment with all-trans retinoic acid (ATRA), but who are found not to have APL, are eligible (treatment with ATRA must be discontinued before starting induction chemotherapy).
2. Diagnosis of AML secondary to prior chemotherapy or radiotherapy for other neoplasms;

3. Prior treatment for AML, except for the following allowances:
    - Leukapheresis;
    - Treatment for hyperleukocytosis with hydroxyurea;
    - Cranial radiotherapy for central nervous system (CNS) leukostasis;
    - Prophylactic intrathecal chemotherapy;
    - Growth factor/cytokine support;
4. Prior treatment with quizartinib or other FLT3-ITD inhibitors;
5. Prior treatment with any investigational drug or device within 30 days prior to Randomization (within 2 weeks for investigational or approved immunotherapy) or currently participating in other investigational procedures;
6. History of known CNS leukemia, including cerebrospinal fluid positive for AML blasts; lumbar puncture is recommended for subjects with symptoms of CNS leukemia to rule out extramedullary CNS involvement;
7. History of other malignancies, except adequately treated non-melanoma skin cancer, curatively treated in-situ disease, or other solid tumors curatively treated with no evidence of disease for at least 2 years;
8. Uncontrolled or significant cardiovascular disease, including any of the following:
    - Bradycardia of less than 50 beats per minute, unless the subject has a pacemaker;
    - Fridericia's Heart Rate Correction Formula (QTcF) interval >450 msec;
    - Diagnosis of or suspicion of long QT syndrome (including family history of long QT syndrome);
    - Systolic blood pressure ≥180 mmHg or diastolic blood pressure ≥110 mmHg;
    - History of clinically relevant ventricular arrhythmias (eg, ventricular tachycardia, ventricular fibrillation, or Torsade de Pointes);
    - History of second (Mobitz II) or third degree heart block (subjects with pacemakers are eligible if they have no history of fainting or clinically relevant arrhythmias while using the pacemaker);
    - History of uncontrolled angina pectoris or myocardial infarction within 6 months prior to Screening;
    - History of New York Heart Association Class 3 or 4 heart failure;
    - Known history of left ventricular ejection fraction (LVEF) ≤45% or less than the institutional lower limit of normal;
    - Complete left bundle branch block;
9. Active acute or chronic systemic fungal, bacterial, or viral infection not well controlled by antifungal, antibacterial or antiviral therapy;

10. Known active clinically relevant liver disease (eg, active hepatitis B, or active hepatitis C);
11. Known history of human immunodeficiency virus (HIV). Subjects should be tested for HIV prior to Randomization if required by local regulations or EC;
12. History of hypersensitivity to any excipients in the quizartinib/placebo tablets;
13. Females who are pregnant or breastfeeding;
14. Otherwise considered inappropriate for the study by the Investigator.

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): ***NCT02668653***

Show 217 Study Locations

Sponsors and Collaborators

Daiichi Sankyo, Inc.

Investigators

Study Director: Global Clinical Leader Daiichi Sankyo, Inc.

More Information

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Responsible Party:	Daiichi Sankyo, Inc.
ClinicalTrials.gov Identifier:	NCT02668653 History of Changes
Other Study ID Numbers:	**AC220-A-U302** 2015-004856-24 (EudraCT Number)
First Posted:	January 29, 2016 Key Record Dates
Last Update Posted:	December 5, 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 Daiichi Sankyo, Inc.:

Newly diagnosed Acute Myeloid Leukemia
FLT3-ITD positive
Chemotherapy
Induction chemotherapy
Consolidation chemotherapy
Maintenance chemotherapy
Quizartinib
Receptor tyrosine kinase inhibitor
Feline McDonough sarcoma (FMS)-like tyrosine kinase 3
AC220
FLT3-ITD
AML

Additional relevant MeSH terms:

Leukemia
Leukemia, Myeloid
Leukemia, Myeloid, Acute
Neoplasms by Histologic Type
Neoplasms
Cytarabine
Daunorubicin
Idarubicin
Antimetabolites, Antineoplastic
Antimetabolites
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents
Antiviral Agents
Anti-Infective Agents
Immunosuppressive Agents
Immunologic Factors
Physiological Effects of Drugs
Antibiotics, Antineoplastic
Topoisomerase II Inhibitors
Topoisomerase Inhibitors
Enzyme Inhibitors