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Efficacy of Oral Azacitidine Plus Best Supportive Care as Maintenance Therapy in Subjects With Acute Myeloid Leukemia in Complete Remission (QUAZAR AML-001)

This study is currently recruiting participants.

Verified March 2014 by Celgene Corporation

Sponsor:
Celgene Corporation

Information provided by (Responsible Party):
Celgene Corporation

ClinicalTrials.gov Identifier:
NCT01757535

First received: November 21, 2012
Last updated: March 4, 2014
Last verified: March 2014
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Study to compare efficacy and safety of oral Azacitidine plus best supportive care versus best supportive care as maintenance therapy in Subjects with Acute Myeloid Leukemia (AML), age = or >55 years, who have achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) after induction with intensive chemotherapy with or without consolidation chemotherapy.

Condition	Intervention	Phase
Leukemia, Myeloid, Acute	Drug: 300 mg Oral Azacitidine Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Compare Efficacy and Safety of Oral Azacitidine Plus Best-supportive Care Versus Best Supportive Care as Maintenance Therapy in Subjects With Acute Myeloid Leukemia in Complete Remission

Resource links provided by NLM:

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

Drug Information available for: Azacitidine

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

U.S. FDA Resources

Further study details as provided by Celgene Corporation:

Primary Outcome Measures:

- Overall Survival (OS) [Time Frame: 60 months] [Designated as safety issue: Yes]

  Number of participants who survive

Secondary Outcome Measures:

- Relapse free survival (RFS) [Time Frame: 60 months] [Designated as safety issue: Yes]

  Number of participants who survive without relapsing

- Complete Remission (CR)/Complete Remission with incomplete blood count recovery (CRi) [Time Frame: 60 months] [Designated as safety issue: No]

  Time to relapse from Complete Remission (CR)/Complete Remission with incomplete blood count recovery (CRi)

- Safety and Tolerability [Time Frame: 60 months] [Designated as safety issue: Yes]

  Number of participants with adverse events

- Healthcare Resource Utilization [Time Frame: 60 months] [Designated as safety issue: No]

  Effect of oral azacitidine compared with Placebo on healthcare utilization. Healthcare utilization data will be collected as described below: Information on each hospitalization will be collected utilizing a CRF designed specifically for this purpose. Information to be collected will include, but not be limited to, the reason for hospitalization (eg, disease relapse, AML-related illness, treatment-related AE), and days of hospitalization by treatment setting (inpatient, special care unit). Other disease- and treatment-related forms of healthcare utilization will be collected through routine study activities. These include diagnostic procedures and treatment interventions not requiring hospitalization such as those required for AML-related illness, or for treatment-related adverse events. Additionally, information on all concomitant medications and resource use associated with treatment administration for AML will be collected. Healthcare resource utilization information will be

- Health-related quality-of-life (HRQoL) [Time Frame: 60 months] [Designated as safety issue: No]

  FACT-F Functional Assessment of Cancer Therapy-Fatigue, EuroQol-5D (EQ-5D) measure of health outcome and 3 additional exploratory questions

Estimated Enrollment:	460
Study Start Date:	December 2012
Estimated Study Completion Date:	August 2018
Estimated Primary Completion Date:	August 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Oral Azacitidine 300mg Oral Azacitidine for the first 14 days of each 28 days treatment cycle	Drug: 300 mg Oral Azacitidine Maintenance therapy
Placebo Comparator: Placebo 300 mg Placebo for the first 14 days of each 28 days treatment cycle	Drug: Placebo

Detailed Description:

This is an international, multicenter, placebo-controlled, phase 3 study with a double-blind, randomized, parallel-group design with de novo AML (Acute Myeloid Leukemia) or AML secondary to prior diagnosis of Myelodysplastic Syndromes (MDS).

Eligibility

Ages Eligible for Study:	55 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Male or female subjects ≥ 55 years of age
2. Newly diagnosed, confirmed de novo AML or AML Secondary to prior MDS
3. First CR/CRi with induction therapy ± consolidation therapy within 90 days of achieving CR
4. Eastern Cooperative Oncology Group (ECOG) performance status - 0, 1, 2, 3

Exclusion Criteria:

1. AML with inv(16), t(8;21), t(16;16), t(15;17), or t(9;22) or molecular evidence of such translocations
2. Prior bone marrow or stem cell transplantation
3. Candidate for allogeneic bone marrow or stem cell transplant
4. Have achieved CR/CRi following therapy with hypomethylating agents
5. Diagnosis of malignant disease within the previous 12 months
6. Proven Central Nervous System (CNS) leukemia

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01757535

Contacts

Contact: Andrew Dorman, Study Manager +1 908-673-2076 adorman@celgene.com

Show 130 Study Locations

Sponsors and Collaborators

Celgene Corporation

Investigators

Study Director: Barry Skikne, MD Celgene Corporation

More Information

No publications provided

Responsible Party:	Celgene Corporation
ClinicalTrials.gov Identifier:	NCT01757535 History of Changes
Other Study ID Numbers:	**CC-486-AML-001**, 2012-003457-28
Study First Received:	November 21, 2012
Last Updated:	March 4, 2014
Health Authority:	United States: Food and Drug Administration Australia: Department of Health and Ageing Therapeutic Goods Administration Austria : Bundesamt für Sicherheit im Gesundheitswesen Belgium: Federal Agency for Medicinal Products and Health Products Canada: Health Canada Czech Republic: State Institute for Drug Control Finland: Finnish Medicines Agency Germany : BfArm : Bundesinstitut fur Arzneimittel und Medizinprodukte Ireland : Irish Medicine Board Israel: Ministry of Health Italy: The Italian Medicines Agency Lithuania: State Medicine Control Agency - Ministry of Health Mexico: Ministry of Health Poland : Office of Registration of Medicinal Products, Medical Devices and Biocidal Products Portugal: National Pharmacy and Medicines Institute South Korea: Korea Food and Drug Administration (KFDA) Spain: Agencia Española de Medicamentos y Productos Sanitarios United Kingdom: Medicines and Healthcare Products Regulatory Agency

Keywords provided by Celgene Corporation:

Maintenance therapy	oral Azacitidine
AML	best supportive care
Acute Myeloid Leukemia	complete remission

Additional relevant MeSH terms:

Leukemia	Antimetabolites
Leukemia, Myeloid, Acute	Molecular Mechanisms of Pharmacological Action
Leukemia, Myeloid	Pharmacologic Actions
Neoplasms by Histologic Type	Antineoplastic Agents
Neoplasms	Therapeutic Uses
Azacitidine	Enzyme Inhibitors
Antimetabolites, Antineoplastic	

ClinicalTrials.gov processed this record on March 04, 2014