Selinexor (KPT-330) in Older Patients With Relapsed AML (SOPRA)

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

Verified June 2015 by Karyopharm Therapeutics, Inc

Sponsor:
Karyopharm Therapeutics, Inc

Information provided by (Responsible Party):
Karyopharm Therapeutics, Inc

ClinicalTrials.gov Identifier:
NCT02088541

First received: March 9, 2014
Last updated: August 18, 2015
Last verified: June 2015
History of Changes

Purpose

This is a randomized, multicenter, open-label, Phase 2 study of the SINE Selinexor given orally versus specified investigator choices (one of three potential salvage therapies). Patients age ≥ 60 years with relapsed/refractory AML of any type except for AML M3, after one prior therapy only, who have never undergone and who are not currently eligible for stem cell transplantation and are currently deemed unfit for intensive chemotherapy.

Condition	Intervention	Phase
Acute Myeloid Leukemia (AML)	Drug: Selinexor Drug: Hydroxyurea Drug: Ara-C Drug: azacitidine Drug: Decitabine	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Randomized Open Label Ph 2 Study of Selective Inhibitor of Nuclear Export (SINE) Selinexor (KPT-330) vs Specified Physician's Choice in Patients ≥ 60 Yrs Old w / Relapsed/Refractory AML Ineligible for Intensive Chemotherapy/Transplantation

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: Hydroxyurea Cytarabine Azacitidine Decitabine

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

U.S. FDA Resources

Further study details as provided by Karyopharm Therapeutics, Inc:

Primary Outcome Measures:

- Overall survival [Time Frame: From the date of randomization until the date of death, or study end (up to approximately 104 weeks)] [Designated as safety issue: No]

  To determine overall survival (OS) of Selinexor as compared to physician choice (PC).

Secondary Outcome Measures:

- 3 month survival [Time Frame: up to 3 months] [Designated as safety issue: No]

  Survival at 3 months post-randomization

Estimated Enrollment:	170
Study Start Date:	March 2014
Estimated Study Completion Date:	January 2017
Estimated Primary Completion Date:	November 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Selinexor (KPT-330) 60 mg twice weekly (Monday and Wednesday or Tuesday and Thursday or Wednesday and Friday).	Drug: Selinexor Other Name: KPT-330
Active Comparator: Physician's Choice One of the following 3 conventional care regimens will be selected by the physician: 1. best supportive care (BSC) including blood product transfusions, antimicrobials, growth factors as needed, and hydroxyurea; 2. BSC + low dose Ara-C, 20 mg bid by subcutaneous (sc) injection daily on days 1-10/14 days (20/28 doses) to be repeated at 28 to 42 day intervals; 3. BSC + hypomethylating agent: azacitidine 75 mg/m2 by sc injection daily on days 1-7 (7 doses) to be repeated at 28 day intervals, or decitabine (20 mg/m2 IV over 1 hour daily on Days 1-5 to be repeated at 28 day intervals).	Drug: Hydroxyurea Other Name: Hydroxycarbamide Drug: Ara-C Other Names: • Cytarabine • cytosine arabinoside • Cytosar-U • Depocyt Drug: azacitidine Other Names: • 5-azacytidine • Vidaza Drug: Decitabine Other Names: • Dacogen • 5-aza-2'-deoxycytidine,

Detailed Description:

This is a randomized, multicenter, open-label phase 2 study of the SINE Selinexor given orally versus restricted investigator choice (i.e., one of three potential salvage therapies).

Patients who have never been transplant eligible, are currently deemed unfit for intensive chemotherapy, ≥ 60 years old, who have AML (except Acute Promyelocytic Leukemia: APL, AML M3) after one prior treatment of either hypomethylating agent or a regimen including Ara-C, and are meeting the inclusion and exclusion criteria will be randomized to receive either oral Selinexor or physician's choice (one of three potential treatments: best supportive care (BSC) alone, or BSC + hypomethylating agent, or BSC + low dose Ara-C until disease progression, death or intolerance has occurred.

Eligibility

Ages Eligible for Study:	60 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Age ≥ 60 years with relapsed/refractory AML of any type except for acute promyelocytic leukemia (APL; AML M3), after at least 1 prior

AML therapy , w ho have never undergone, and w ho are not currently eligible for, stem cell transplantation, and are currently deemed unfit for intensive chemotherapy.

- ECOG ≤ 2.
- Must have available archival or recently acquired bone marrow biopsy/aspiration or tumor tissue for central review to be eligible.
- Relapsed or refractory AML, defined as either: recurrence of disease after a complete remission (CR), or failure to achieve CR w ith initial therapy.
- Must have received at least 1 prior line of AML therapy given at standard doses and must have progressed after their most recent therapy. Prior therapy must have included: a hypomethylating agent w ith at least 2 cycles.
- At least 2 w eeks must have elapsed since the last anti-leukemia treatment (w ith the exception of hydroxyurea) before first dose in this study.

Exclusion Criteria:

- Treatment w ith any investigational agent w ithin 3 w eeks prior to first dose in this study.
- Presence of central nervous system (CNS) leukemia.
- In blast transformation of chronic myeloid leukemia (CML). Prior myelodysplastic syndrome (MDS) is acceptable; prior treatment for MDS does not count as an AML therapy.
- Major surgery w ithin 2 w eeks of first dose of study drug. Patients must have recovered from the effects of any surgery performed greater than 2 w eeks previously.
- Concurrent active malignancy under treatment.
- Know n active hepatitis B virus (HBV) or C virus (HCV) infection; or know n to be positive for HCV ribonucleic acid (RNA) or HBsAg (HBV surface antigen).
- Know n HIV infection.
- Unable to sw allow tablets, or patients w ith malabsorption syndrome, or any other disease significantly affecting gastrointestinal function.
- Patients w hose AML is classified as favorable according to the European LeukemiaNet (ELN) disease risk assessment.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk w ith 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: NCT02088541

Show 66 Study Locations

Sponsors and Collaborators

Karyopharm Therapeutics, Inc

More Information

No publications provided

Responsible Party:	Karyopharm Therapeutics, Inc
ClinicalTrials.gov Identifier:	NCT02088541 History of Changes
Other Study ID Numbers:	**KCP-330-008**
Study First Received:	March 9, 2014
Last Updated:	August 18, 2015
Health Authority:	United States: Food and Drug Administration Canada: Health Canada Denmark: Danish Health and Medicines Authority Germany: Federal Institute for Drugs and Medical Devices Spain: Ministerio de Sanidad, Servicios Sociales e Igualdad Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) United Kingdom: Medicines and Healthcare Products Regulatory Agency Israel: Ministry of Health

Keyw ords provided by Karyopharm Therapeutics, Inc:

Relapsed/Refractory Acute Myeloid Leukemia	Karyopharm
Acute Myeloid Leukemia	Selinexor
AML	KPT-330

Additional relevant MeSH terms:

Leukemia, Myeloid
Leukemia, Myeloid, Acute
Leukemia
Neoplasms
Neoplasms by Histologic Type
Azacitidine
Decitabine
Hydroxyurea
Antimetabolites
Antimetabolites, Antineoplastic
Antineoplastic Agents
Antisickling Agents
Enzyme Inhibitors
Hematologic Agents
Molecular Mechanisms of Pharmacological Action
Nucleic Acid Synthesis Inhibitors
Pharmacologic Actions
Therapeutic Uses

ClinicalTrials.gov processed this record on January 07, 2016