ForPatients
by Roche

Leukemia

A Study of Idasanutlin With Cytarabine Versus Cytarabine Plus Placebo in Participants With Relapsed or Refractory Acute Myeloid Leukemia (AML)

Trial Status	Trial Runs In	Trial Identifier
Terminated	19 Countries	NCT02545283 2014-003065-15 WO29519

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Phase III Study of Idasanutlin, an MDM2 Antagonist, With Cytarabine Versus Cytarabine Plus Placebo in Patients With Relapsed or Refractory Acute Myeloid Leukemia (AML)

Trial Summary:

This is a multicenter, double-blind, randomized, placebo-controlled study designed to compare overall survival in participants with relapsed or refractory AML treated with idasanutlin in combination with cytarabine versus participants treated with placebo and cytarabine. Participants will receive induction treatment with idasanutlin/placebo and cytarabine (Cycle 1). Responding participants may continue to receive a maximum of further two cycles of consolidation (Cycle 2 and Cycle 3). Complete remission (CR), CR with incomplete platelet count recovery (CRp), overall remission rate (ORR), event-free survival (EFS) and percentage of participants with an allogeneic hematopoietic stem cell transplant (HSCT) will also be compared between treatment arms. This study will include participants with and without TP53 wild type (TP53 WT) mutations.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Documented/confirmed first/second refractory/relapsed AML using World Health Organization classification, except acute promyelocytic leukemia
- No more than 2 prior induction regimens (excluding prior HSCT) in their first line treatment and one must have included cytarabine with an anthracycline (or anthracenedione)
- Eastern Cooperative Oncology Group performance status of 0 to 2
- Adequate hepatic and renal function
- White blood cell (WBC) count at randomization less than or equal to (</=) 50000 cells per cubic millimeter (/mm^3)

Exclusion Criteria:

- First relapsed participants aged less than (<) 60 years with first CR duration greater than (>) 1 year
- Participants with prior documented antecedent hematological disorder (AHD)
- AML secondary to any prior chemotherapy unrelated to leukemia
- Participants who are either refractory to or relapsed within 90 days of receiving a regimen containing a cumulative dose of greater than or equal to (>/=) 18 g/m^2 of cytarabine
- Participants who have received allogeneic HSCT within 90 days prior to randomization
- Participants who have received immunosuppressive therapy for graft versus host disease or for engraftment syndrome after autologous stem cell transplantation within 2 weeks prior to randomization
- Prior treatment with an Murine Double Minute 2 (MDM2) antagonist
- Participants receiving any other investigational or commercial agents or therapies administered with the intention to treat their malignancy within 30 days from first receipt of study drug
- Participants with a history of other malignancy within 5 years prior to screening except for malignancy that has been in remission without treatment for at least 2 years prior to randomization
- Participants who have any severe and/or uncontrolled medical conditions or other conditions that could affect their participation in the study
- Participants with extramedullary AML with no evidence of systemic involvement
- Pregnant or breastfeeding participants