

Leukemia

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

**Trial Status**  
Terminated

**Trial Runs In**  
19 Countries

**Trial Identifier**  
NCT02545283 2014-003065-15  
WO29519

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

### ***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**  
Sponsor

**Phase 3**  
Phase

**NCT02545283 2014-003065-15 WO29519**  
Trial Identifiers

### ***Eligibility Criteria:***

**Gender**  
All

**Age**  
≥ 18 Years

**Healthy Volunteers**  
No