

Cancer

A Study to Investigate the Bioequivalence or Relative Bioavailability of Three New Idasanutlin Tablet Variants Following Oral Administration in Participants With Solid Tumors

Trial Status
Completed

Trial Runs In
2 Countries

Trial Identifier
NCT03362723 NP39051

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 multi-center, open-label, pharmacokinetic study will evaluate the bioequivalence (BE) or relative bioavailability (rBA) of three new idasanutlin-tablet variants compared to the reference tablet formulation following oral administration of a 300 milligrams (mg) dose in participants with solid tumors for whom no further treatment options are available. Following the four administrations of idasanutlin in the BE/rBA cycle of the study (Cycle 1), participants who have no clinically defined progressive disease and who recover from any prior treatment toxicity to Grade less than or equal to (\leq) 1 may enter the optional treatment extension phase. This extension phase will continue for additional 28-day cycles or until disease progression or unacceptable toxicity is observed.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT03362723 NP39051
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
 \geq 18 Years

Healthy Volunteers
No