## **ForPatients**

by Roche

## 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	Trial Runs In	Trial Identifier
Completed	2 Countries	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 (</=) 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 >= 18 Years		Healthy Volunteers	