ForPatients
by Roche

Solid TumorsCancer

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 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 Multi-Center, Open-Label, Clinical Pharmacology Study for Idasanutlin, an MDM2 Antagonist With a Hybrid Randomized/Sequential, Single-Dose, 4-Period, Crossover Design to Investigate the Bioequivalence or Relative Bioavailability of Three New Idasanutlin Tablet Variants Following Oral Administration in Patients With Solid Tumors

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	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Participant must have histologically or cytologically confirmed advanced malignancies, except all forms of leukemia and lymphoma, for which standard curative or palliative measures do not exist, are no longer effective, or are not acceptable to the participant
- Measureable or evaluable disease by RECIST v1.1 for solid tumors prior to the administration of study drug
- Ability to understand and willingness to sign a written informed consent form and comply with all study requirements
- Life expectancy of greater than or equal to (>/=)12 weeks
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1
- New York Heart Association (NYHA) status of less than or equal to (</=)1
- Women of childbearing potential and men should remain abstinent or agree to use an effective form of contraception and to continue its use for the duration of study treatment and for a period of time after the last dose of study treatment
- Adequate bone marrow function, hepatic function, and renal function

Exclusion Criteria:

- Participants with prostate cancer who are unable to interrupt treatment with ketoconazole; ketoconazole treatment must be discontinued 2 weeks prior to first dose of study medication and is not allowed during Cycle 1, but may be used in the optional extension phase.
- Administration of investigational agents or investigational drugs </=4 weeks or less than (<)5 times the terminal half-life prior to study treatment start, whichever is longer
- Active gastrointestinal (GI) conditions and uncontrolled irritable bowel disease or pre-existing GI disorders that may interfere with proper absorption of the study drug
- History of allergic reactions attributed to components of the formulated product
- History of seizure disorders or unstable central nervous system metastases
- Presence of any severe and/or uncontrolled medical conditions or other conditions that could affect their participation in the study
- Evidence of electrolyte imbalance
- Pregnant or breast feeding
- Known coagulopathy, platelet disorder or history of non-drug-induced thrombocytopenia
- Current treatment with oral or parenteral anti-coagulants/antiplatelet agents
- Acute toxicities from any prior anti-tumor therapy, surgery, or radiotherapy that has not resolved to Grade </=2, except alopecia
- Last dose of prior anti-tumor therapy <21 days prior to the first administration of idasanutlin or <5 times terminal half-life of that therapy, whichever is shorter
- Refusal to potentially receive blood products and/or have a hypersensitivity to blood products
- Known bone marrow disorders which may interfere with bone marrow recovery or participants with delayed recovery from prior chemoradiotherapy
- Planned procedure or surgery during the study
- History of human immunodeficiency virus (HIV), hepatitis B, or hepatitis C
- Blood transfusion within 4 weeks prior to screening
- History or presence of an abnormal electrocardiogram (ECG) that is clinically significant in the investigator's opinion
- History of ventricular dysrhythmias or risk factors for ventricular dysrhythmias
- Current treatment with medications that are well known to prolong the QT interval