ForPatients *by Roche*

Polycythemia Vera

A Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Idasanutlin Monotherapy in Participants With Hydroxyurea-Resistant/Intolerant Polycythemia Vera

Trial Status	Trial Runs In	Trial Identifier
Terminated	4 Countries	NCT03287245 2017-000861-58
		NP39761

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 an open-label, single-arm study of idasanutlin monotherapy in participants with hydroxyurea (HU)-resistant/intolerant Polycythemia vera (PV). The study will include two phases: initial phase and expansion phase. The initial phase will assess the safety and efficacy of idasanutlin monotherapy in ruxolitinib naïve and ruxolitinib-resistant or intolerant patients, respectively. If the initial phase shows promising results for ruxolitinib-resistant or intolerant patients, an expansion phase will be opened to further characterize the efficacy of idasanutlin.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT03287245 2017-000861-58 NP39761 Trial Identifiers

Eligibility Criteria:

Gender

Age >= 18 Years Healthy Volunteers