ForPatients
by Roche

Cancer

A Study to Evaluate the Efficacy and Safety of Vismodegib in Combination With Ruxolitinib for the Treatment of Intermediate- or High-Risk Myelofibrosis (MF)

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT02593760 2015-001620-33 WO29806

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 multicenter, randomized, double-blind, placebo-controlled study will evaluate the efficacy and safety of vismodegib plus (+) ruxolitinib versus placebo + ruxolitinib in participants with intermediate- or high-risk MF. The study will be divided into 2 components. The Phase Ib portion of the study consists of participants receiving open-label vismodegib (150 milligrams [mg] orally [PO] once daily [QD]) + ruxolitinib (PO twice daily [BID]). A safety assessment will be performed after the first 10 participants have been treated for 6 weeks. An analysis for efficacy and safety is planned in the first 10 participants at Week 24. There will be a hold on participant screening and enrollment during this assessment. Another 10 participants may be enrolled, thereafter, to further assess efficacy and safety (at Week 24) before the initiation of the Phase III randomization portion of the study. Similarly, there will be another hold on participant screening and enrollment during this assessment. The participants enrolled in the Phase Ib portion of the study will continue to receive vismodegib (150 mg PO QD) + ruxolitinib (PO BID) for up to 48 weeks, if clinical benefit is observed after 24 weeks. The Phase III randomized, double-blind portion of the study will enroll approximately 84 participants. Participants will be randomly assigned in a 1:1 ratio (double blind) to receive either vismodegib (150 mg PO QD) + ruxolitinib (PO BID) or placebo (PO QD) + ruxolitinib (PO BID) for up to 48 weeks.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	**>= 18 Years**	**No**