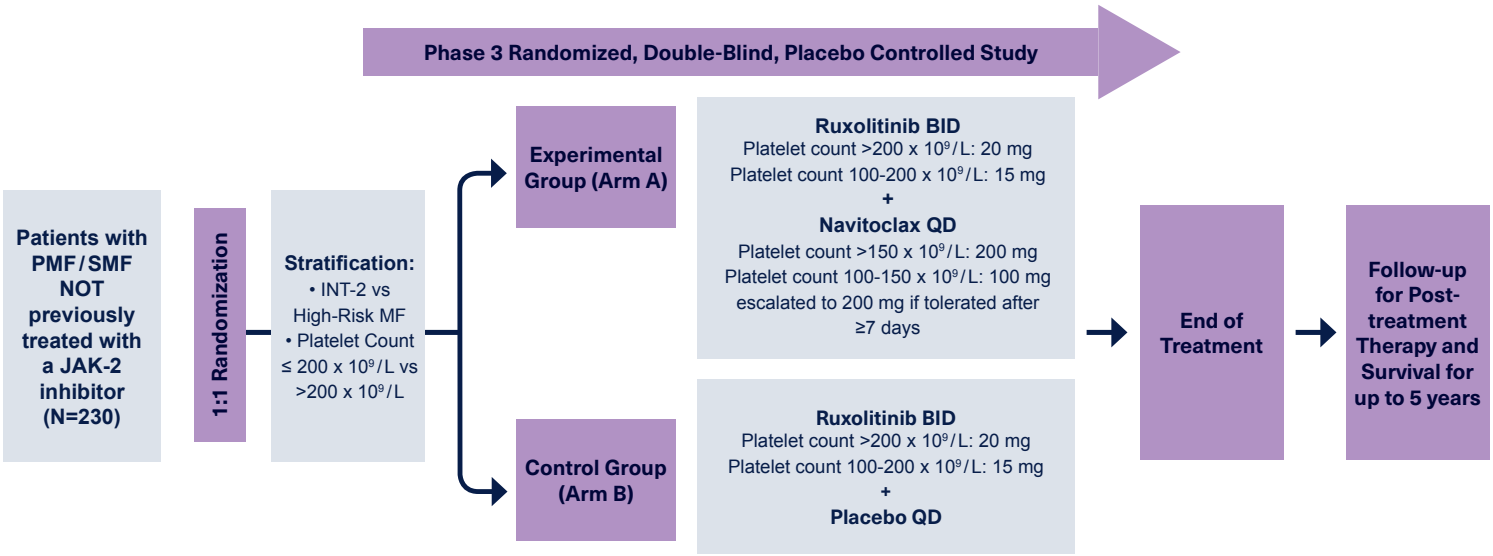
Myelofibrosis (MF)

M16-191
Study Design and Endpoints

Phase 3

A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study Of Navitoclax In Combination With Ruxolitinib Versus Ruxolitinib In Subjects With Myelofibrosis (TRANSFORM-1) (NCT04472598)

Transform 1
M16-191



Key Inclusion Criteria

- Intermediate-2 or high risk (DIPSS+) primary MF, post-polycythemia vera MF or post-essential thrombocythemia MF.
- Ineligible for stem cell transplantation at time of study entry
- ≥2 symptoms with a score ≥3, or a total score of ≥12, as measured by the MFSAF v4.0.
- Splenomegaly
- ECOG performance status 0-2

Key Exclusion Criteria

- Prior treatment with a JAK-2 inhibitor
- Prior treatment with a BH3-mimetic compound or BET inhibitor or stem cell transplant.
- Receiving medication that interferes with coagulation or platelet function except for low dose aspirin (up to 100 milligram daily) and low molecular weight heparin (LMWH) within 3 days prior to the first dose of study drug or during the study treatment period.
- Leukemic transformation (>10% blasts in peripheral blood or bone marrow).

Navitoclax is an investigational drug that is not approved by the FDA or any Regulatory Health Agencies. Safety and Efficacy have not been established.

Primary Endpoint

- Percentage of participants who achieve Spleen Volume Reduction of at least 35% at Week 24 (SVR_{35}).

To learn more about these studies, please visit **https://ClinicalTrials.gov** or email **abbvieclinicaltrials@abbvie.com**

BET = Bromodomain and Extra-Terminal; BID = Twice Daily; DIPSS+ = Dynamic International Prognostic Scoring System Plus; ECOG = Eastern Cooperative Group; INT = Intermediate; JAK-2 = Janus Kinase-2; MF = Myelofibrosis; MFSAF = Myelofibrosis Symptom Assessment Form; PMF = Primary Myelofibrosis; QD = Daily; SMF = Secondary Myelofibrosis

https://clinicaltrials.gov/ct2/show/NCT04472598 (accessed August 2021)

Potluri J, et al. Poster #3002. 62nd ASH Annual Meeting and Exposition; December 5-8, 2020; Virtual Format.

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