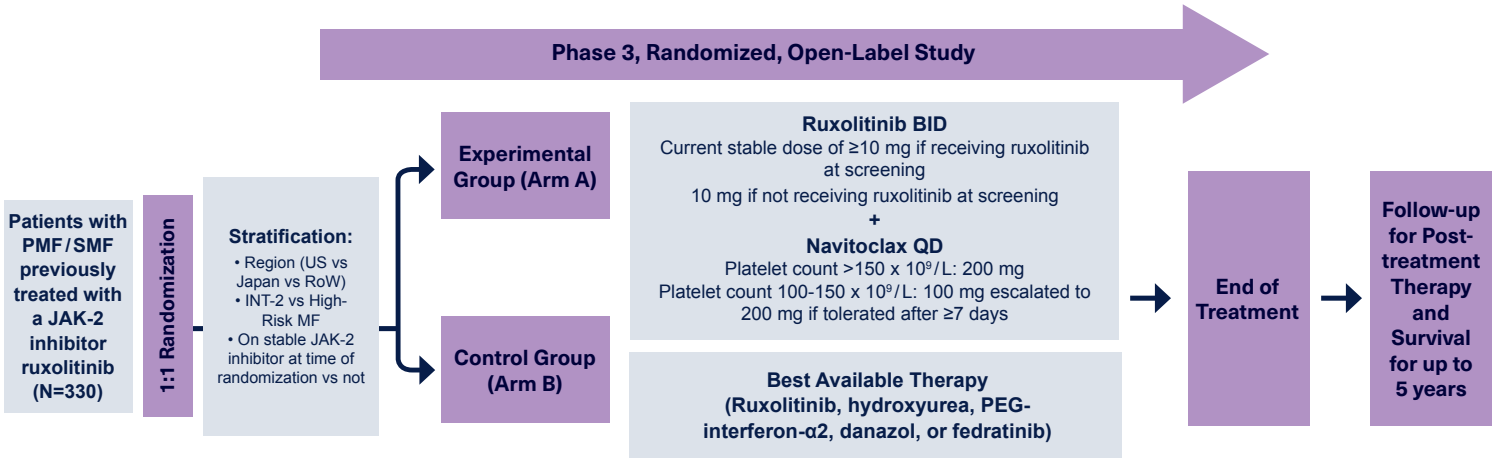
Myelofibrosis (MF)

M20-178
Study Design and Endpoints

Phase 3

A Randomized, Open-Label, Phase 3 Study Evaluating Efficacy and Safety of Navitoclax in Combination With Ruxolitinib Versus Best Available Therapy in Subjects With Relapsed / Refractory Myelofibrosis (TRANSFORM-2) (NCT04468984)

TRANSFORM 2
M20-178



Key Inclusion Criteria

- Intermediate-2 or high risk (DIPSS+) primary MF, post-polycythemia vera MF or post-essential thrombocythemia MF.
- Not candidate for stem cell transplantation
- At least 2 symptoms with a score of ≥3 or a total score of ≥12, as measured by the MFSAF v4.0.
- Must have received prior treatment with a single JAK-2 inhibitor, ruxolitinib, and meet one of the following criteria:
  - Prior treatment with ruxolitinib for ≥24 weeks that was stopped due to loss of spleen response (refractory), or loss of spleen response or symptom control after a previous response (relapsed), or was continued despite relapsed / refractory status.
  - Prior treatment with ruxolitinib for <24 weeks with documented disease progression while on therapy.
- Splenomegaly
- Prior or current treatment with ruxolitinib for ≥ 28 days with intolerance defined as new RBC transfusion requirement (at least 2 units / month for 2 months) while receiving a total daily ruxolitinib dose of ≥ 30 mg but unable to reduce dose further due to lack of efficacy.

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**

Key Exclusion Criteria

- Received prior treatment with a BH3-mimetic compound, BET inhibitor, or prior use of > 1 JAK-2 inhibitor or stem cell transplant.
- Receiving medication that interferes with coagulation or platelet function except for low dose aspirin (up to 100 milligrams daily) and low molecular weight heparin (LMWH) within 3 days prior to the first dose of study drug or during the study treatment period.
- Platelets <100 x 10⁹ / L
- Receiving anticancer therapy including chemotherapy, radiation therapy, hormonal therapy (with the exception of hormones for thyroid conditions or estrogen replacement therapy) within 30 days prior to first dose of study drug, and during the study treatment period (other than any overlapping therapy as part of the selected BAT).
- 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.

BET = Bromodomain and Extra-Terminal; BID = Twice Daily; DIPSS+ = Dynamic International Prognostic Scoring System Plus; INT = Intermediate; JAK-2 = Janus kinase-2; MF = Myelofibrosis; MFSAF = Myelofibrosis Symptom Assessment Form; PMF = Primary Myelofibrosis; QD = Daily; RBC = Red Blood Cell; SMF = Secondary Myelofibrosis

https://clinicaltrials.gov/ct2/show/NCT04468984 (accessed August 2021)

Potluri J, et al. Poster #1255. 62nd ASH Annual Meeting and Exposition; December 5-8, 2020; Virtual Format.

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