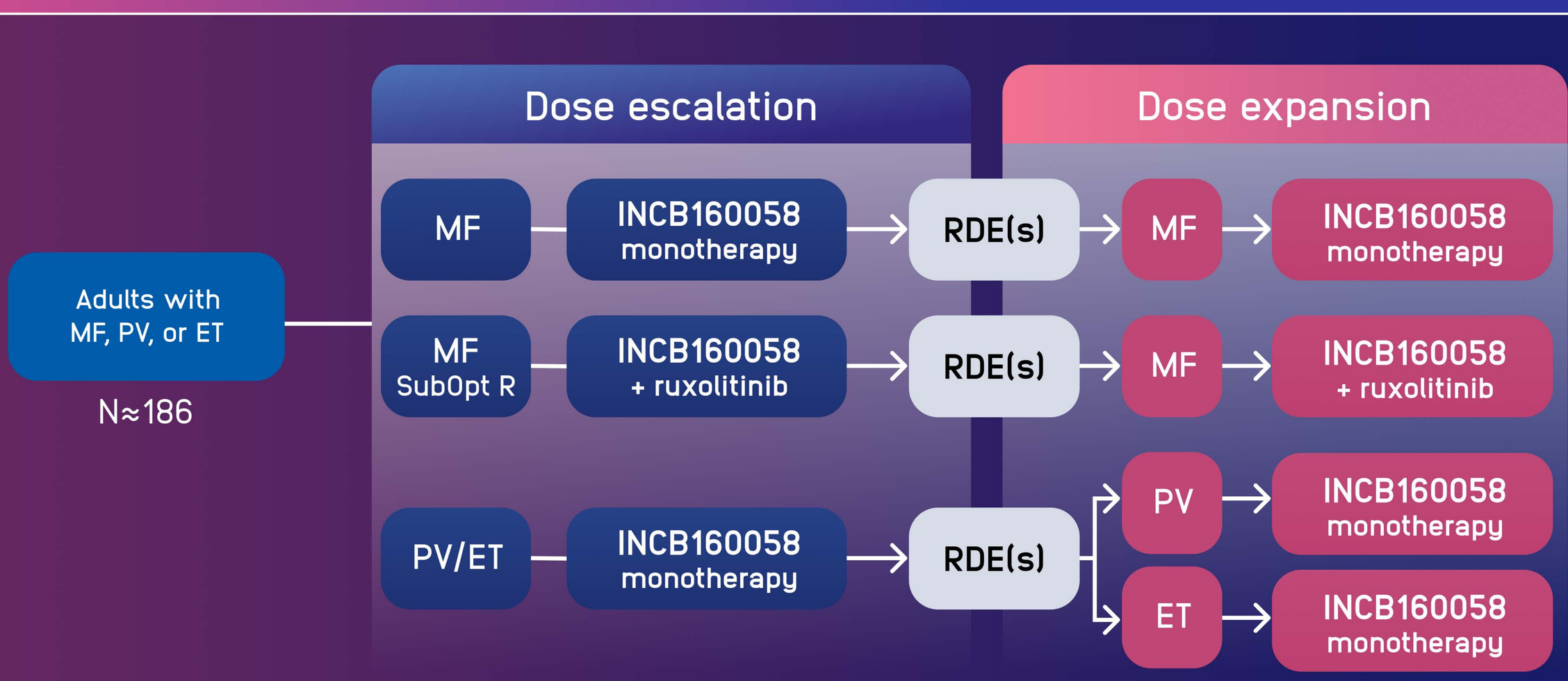
INCB160058 (JAK2V617F Mutant–Selective Inhibitor)[1,2]

Population: patients with MF, PV, or ET

Phase 1
ClinicalTrials.gov ID: NCT06313593
Study ID: INCB160058-101



PRIMARY ENDPOINTS

Dose-limiting toxicities

TEAEs

TEAEs leading to dose modification or discontinuation

SELECT SECONDARY ENDPOINTS

Patients with MF:

- Response per IWG-MRT and ELN criteria
- SVR

Patients with PV/ET:

- Response per IWG-MRT and ELN criteria

All patients:

- PK parameters
- Change in MPN-SAF TSS

SELECT INCLUSION CRITERIA[a]

- Documented *JAK2*V617F mutation
- Confirmed diagnosis of MF, PV, or ET
- **Patients with MF:**
  - DIPSS intermediate-1–risk or greater primary MF or MYSEC-PM intermediate-1–risk or greater secondary MF
  - MF monotherapy cohort: previously treated with ≥1 JAKi for ≥12 weeks and resistant, refractory, or lost response to or intolerant of JAKi treatment
  - MF SubOpt R cohort: previously treated with ruxolitinib for ≥12 weeks, at a stable dose for ≥8 weeks, and unlikely to benefit from further ruxolitinib monotherapy
  - Radiological confirmation of splenomegaly or palpable spleen ≥5 cm below left subcostal margin
- **Patients with PV/ET:** previously treated with ≥1 standard cytoreductive therapy and resistant, refractory, lost response to, or intolerant of treatment
- **Patients with ET:**
  - High risk, defined as: age ≥60 years; history of arterial or venous thrombosis; history of major bleeding (related to the underlying disease); or bleeding risk, defined as platelet count >1×10^{12}/L
  - Platelet count >450×10^{9}/L

SELECT EXCLUSION CRITERIA[a]

- Presence of any hematologic malignancy other than MF, PV, or ET
- History of major bleeding or thrombosis within the last 3 months prior to study enrollment
- Prior allogeneic or autologous HSCT or planned allogeneic HSCT
- Active invasive malignancy
- Significant concurrent, uncontrolled medical condition
- Acute or chronic HBV, active HCV, or known history of HIV infection
- Any prior MPN-directed therapy within 5 half-lives or 28 days prior to the first dose of study treatment (whichever is shorter)
- Treatment with G-CSF or GM-CSF, romiplostim, or eltrombopag at any time ≤4 weeks before the first dose of study treatment

[a] Regional differences may apply for select criteria.

The efficacy and safety of the investigational compound discussed have not been established. There is no guarantee that this compound will become commercially available for the uses under investigation.

For more information, visit IncyteClinicalTrials.com or contact us at 1-855-4MED-INFO (855-463-3463) or clintrials@incyte.com

A copy of this panel can be accessed using the QR code:

DIPSS, Dynamic International Prognostic Scoring System; ELN, European LeukemiaNet; ET, essential thrombocythemia; G-CSF, granulocyte colony-stimulating factor; GM-CSF, granulocyte-macrophage colony-stimulating factor; HBV, hepatitis B virus; HCV, hepatitis C virus; HSCT, hematopoietic stem cell transplant; IWG-MRT, International Working Group for Myeloproliferative Neoplasms Research and Treatment; JAK, Janus kinase; JAKi, JAK inhibitor; MF, myelofibrosis; MPN, myeloproliferative neoplasm; MPN-SAF TSS, Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score; MYSEC-PM, Myelofibrosis Secondary to PV and ET-Prognostic Model; PK, pharmacokinetics; PV, polycythemia vera; RDE, recommended dose for expansion; SubOpt R, suboptimal response to ruxolitinib; SVR, spleen volume response; TEAE, treatment-emergent adverse event.

1. ClinicalTrials.gov. Accessed Mar 2026. https://clinicaltrials.gov/study/NCT06313593. 2. Gotlib J, et al. *Blood*. 2025;146(suppl 1):2051.

This information is current as of March 23, 2026.