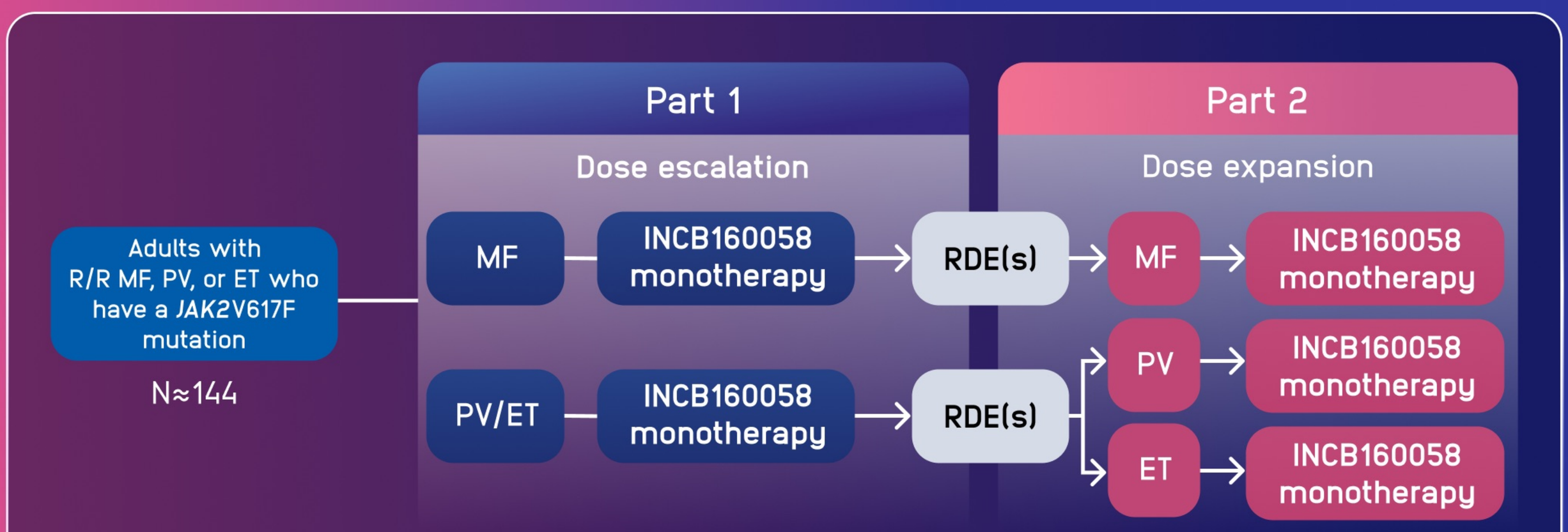
INCB160058 (JAK2V617F Mutant–Specific Inhibitor)[1]

Population: patients with MF, PV, or ET

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



PRIMARY ENDPOINTS

Dose-limiting toxicities

Incidence of TEAEs

Incidence of TEAEs leading to dose modification or discontinuation

SELECT SECONDARY ENDPOINTS

Patients with MF:
- Response[a]
- SVR

Patients with PV/ET:
- Response[a]

All patients:
- PK parameters
- Change in MPN-SAF TSS

[a] Per revised IWG-MRT and ELN criteria (2013).[1,2]

SELECT INCLUSION CRITERIA

- Confirmed diagnosis of MF, PV, or ET
- Documented *JAK2*V617F mutation
- **Patients with MF:**
  - DIPSS/DIPSS-Plus intermediate-1 or greater MF or MYSEC-PM intermediate-1 or greater secondary MF[2]
  - Previously treated with ≥1 JAKi for ≥12 weeks and resistant, refractory, lost response to, or intolerant of JAKi treatment
  - Radiologic confirmation of splenomegaly or palpable spleen ≥5 cm below left subcostal margin[2]
- **Patients with PV/ET:** previously treated with ≥1 standard cytoreductive therapy and resistant, refractory, lost response to, or intolerant of treatment
- **Patients with ET:**[2]
  - 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

- **For patients with MF and PV:**[2] PLT <50×10^{9}/L
- 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 allogenic or autologous HSCT or planned allogenic HSCT
- Active invasive malignancy
- Significant concurrent, uncontrolled medical condition
- Active HBV/HCV infection or known history of HIV infection
- Any prior MF-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

INCB160058-101 | INCA33989-101/-102 | INCB57643-103

The efficacy and safety of the investigational compounds discussed have not been established. There is no guarantee that these compounds 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-Myeloproliferative Neoplasms Research and Treatment; JAK, Janus kinase; JAKi, JAK inhibitor; MF, myelofibrosis; MPN-SAF TSS, Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score; MYSEC-PM, Myelofibrosis Secondary to PV and ET-Prognostic Model; PK, pharmacokinetic; PV, polycythemia vera; RDE, recommended dose for expansion; R/R, relapsed/refractory; SVR, spleen volume response; TEAE, treatment-emergent adverse event.

1. ClinicalTrials.gov. Accessed May 2025. https://clinicaltrials.gov/study/NCT06313593. 2. Data on file. Incyte Corporation.

This information is current as of May 12, 2025.