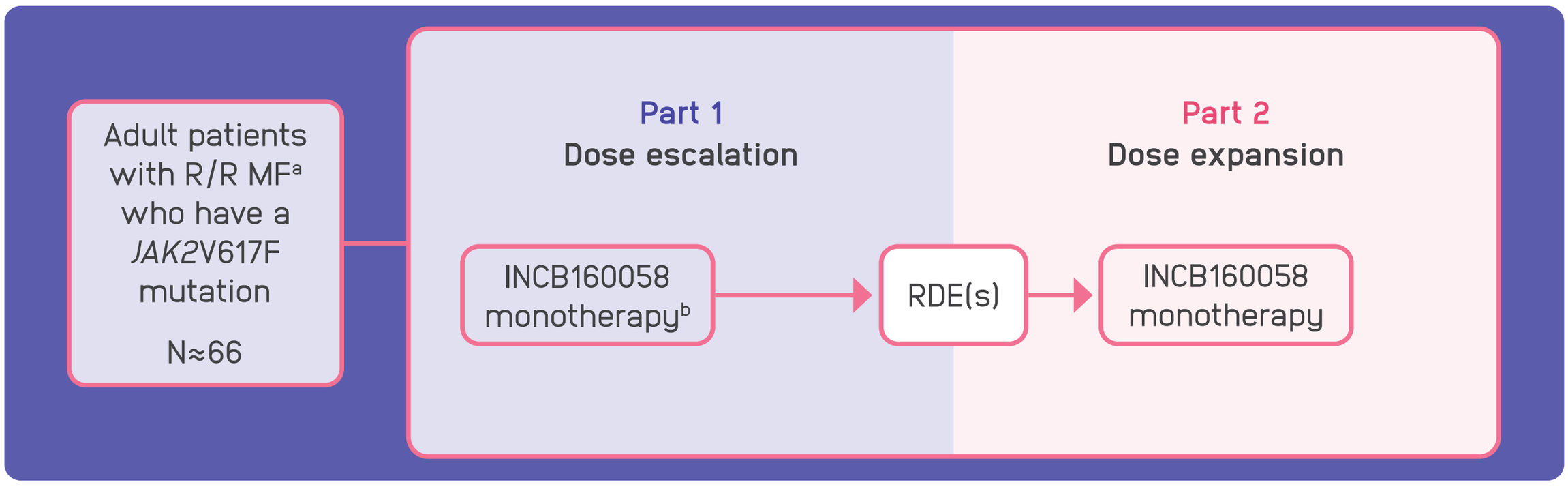
INCB160058-101

Myelofibrosis
Phase 1 | NCT06313593

INCB160058 (JAK2V617F-Selective Inhibitor) Monotherapy in Patients With MF[1,2]

A Safety and Tolerability Study



[a] R/R MF as defined in the protocol. [b] INCB160058 will be administered in a protocol-defined starting regimen to identify the MTD and/or RDE(s).

Primary endpoints

- Dose-limiting toxicities
- Incidence of TEAEs
- TEAEs leading to dose reduction or discontinuations

Secondary endpoints

- PK parameters
- Response per revised IWG-MRT and ELN criteria for MF
- SVR
- Symptom response
- Anemia response

Select inclusion criteria

- Histologically confirmed PMF, post-PV MF, or post-ET MF
- Documented *JAK2*V617F mutation
- Minimum burden of disease based on symptoms and/or splenomegaly
- Previous treatment with ≥1 JAKi for ≥12 weeks and disease resistant/refractory to, intolerant of, or with lost response

Select exclusion criteria

- Presence of any hematologic malignancy other than PMF, post-PV MF, or post-ET MF
- 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

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 below.

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; MTD, maximum tolerated dose; PK, pharmacokinetic; PMF, primary myelofibrosis; 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 Jul 2024. https://www.clinicaltrials.gov/study/NCT06313593 2. Data on file. Incyte Corporation.

This information is current as of July 25, 2024.