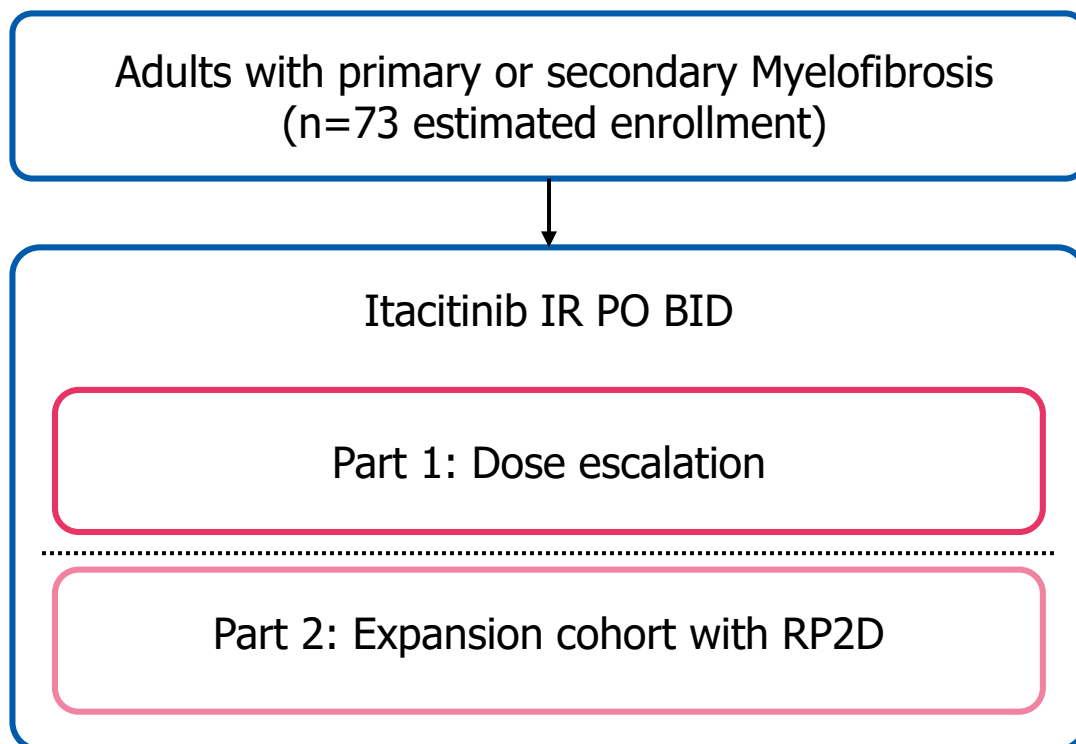


2-part, open-label, non-randomized study evaluating Itacitinib immediate release in patients with primary or secondary myelofibrosis who have received prior Rituximab and/or Fedratinib monotherapy



**Primary end point**

- Part 1: TEAEs (24 weeks time frame)
- Part 2: Spleen Volume Reduction (time frame 24 weeks)

**Secondary end points Part 2**

- TEAEs
- Improvement in TSS (24 weeks)
- Improvement in QoL
- Improvement in Patient Global Impression of Change (PGIC)

**Select inclusion criteria**

- Age ≥18
- Diagnosis of PMF or secondary MF (PPV-MF, PET-MF)
- DIPSS risk category of ≥ intermediate-1
- Prior treatment with and currently receiving Ruxolitinib and/or Fedratinib monotherapy
- Palpable spleen ≥ 5 cm BLCM or ≥450 cm<sup>3</sup> volume
- Allogenic stem cell transplant not planned
- Platelets ≥50 x 10<sup>9</sup>/L

**Select exclusion criteria**

- Prior therapy with JAK inhibitor other than Ruxolitinib or Fedratinib
- ≥10% myeloid blasts in peripheral blood or bone marrow prior to or at screening
- Unability to be tapered from Ruxolitinib/Fedratinib treatment over the course of 14 days without corticosteroids, hydroxyurea or other agents
- Prior treatment with Ruxolitinib/Fedratinib/other MF-directed therapy within 2 weeks of Day 1

**The efficacy and safety of the investigational compound discussed<sup>a</sup> have not been established. There is no guarantee that this compound<sup>a</sup> will become commercially available for the use(s) under investigation.**

For more information, visit [IncyteClinicalTrials.com](https://www.incyteclinicaltrials.com), contact us at +800 00027423 or by email at [clintrials@incyte.com](mailto:clintrials@incyte.com), or click on the QR code on the right to visit the trial on [clinicaltrials.gov](https://www.clinicaltrials.gov)

**For reporting adverse events, contact [eumedinfo@incyte.com](mailto:eumedinfo@incyte.com) or +49 8007239013**



<sup>a</sup> Itacitinib  
 BID: Twice a day; BLCM: below left costal margin; DIPSS: Dynamic International Prognostic Scoring System; IR: Immediate Release; JAK: janus kinase; MF: Myelofibrosis; PET: Post Essential Thrombocythemia; PMF: Primary MF; PO: Peroral; PPV: Post Polycythemia Vera; Prim. Compl.: Primary completion; QoL: Quality of Life; RP2D: Recommended Phase 2 dose; TEAEs: Treatment emergent adverse events; TSS: Total Symptom Score; <https://www.clinicaltrials.gov/ct2/show/NCT04629508>, Accessed 17 March, 2021