LIMBER

LEADING IN MPNS BEYOND RUXOLITINIB

NCT04629508| Phase 2 | Myelofibrosis

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

Adults with primary or secondary Myelofibrosis
(n=73 estimated enrollment)

↓

Itacitinib IR PO BID

Part 1: Dose escalation

Part 2: Expansion cohort with RP2D

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^3 volume
- Allogenic stem cell transplant not planned
- Platelets ≥50 x 10^9/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[a] have not been established. There is no guarantee that this compound[a] will become commercially available for the use(s) under investigation.

For more information, visit IncyteClinicalTrials.com, contact us at +800 00027423 or by email at clintrials@incyte.com, or click on the QR code on the right to visit the trial on clinicaltrails.gov

For reporting adverse events, contact eumedinfo@incyte.com or +49 8007239013

[a] 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

DE/TAFACD19/NP/21/0013, 26 March 2021