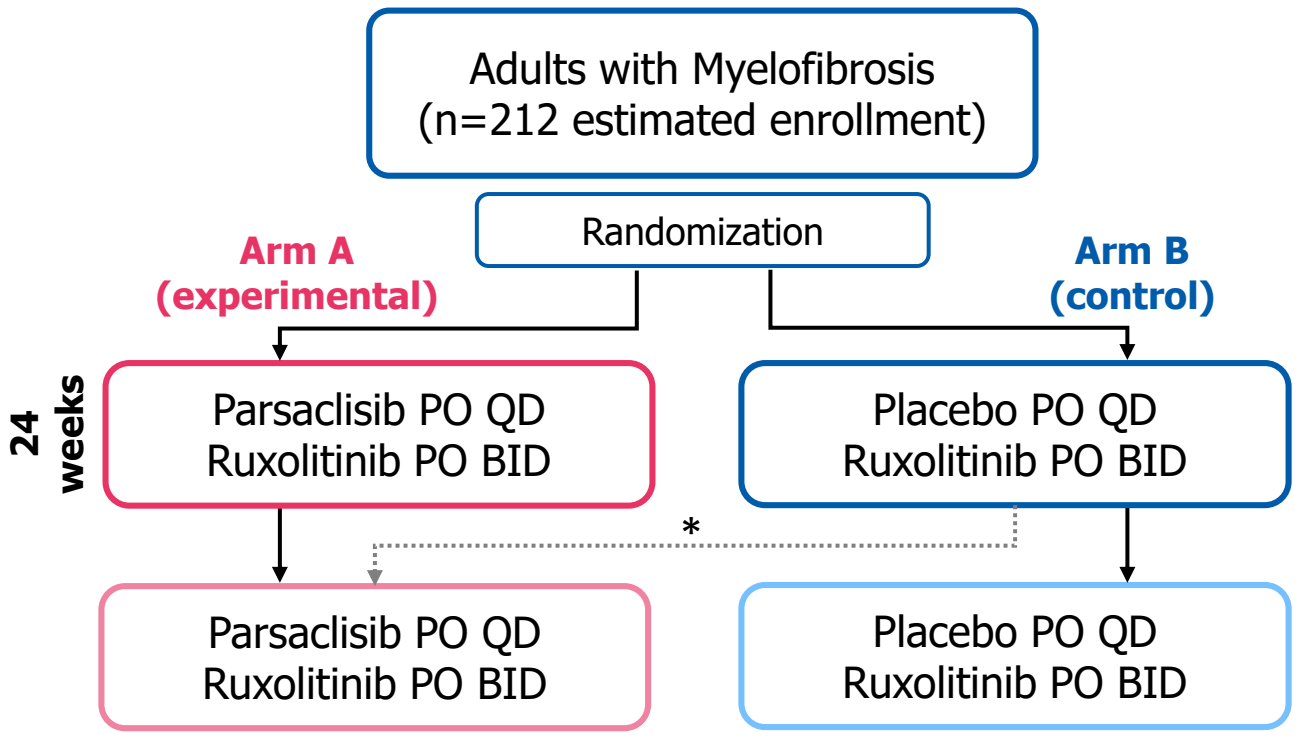
LIMBER

LEADING IN MPNS BEYOND RUXOLITINIB

NCT04551053| Phase 3 | Myelofibrosis

Incyte

Double-blind, Placebo-controlled, randomized study evaluating Ruxolitinib in combination with Parsaclisib (PI3Kδ inhibitor) in patients with suboptimal response to Ruxolitinib



* Crossover allowed after 24 weeks

Primary end point

- Spleen volume reduction (baseline to week 24)

Secondary end points

- Proportion of patients achieving targeted reduction in TSS (baseline to week 24)
- Change in TSS, Time to 1st ≥50% reduction in TSS
- Time of onset and duration of maintanence of targeted reduction of spleen volume
- OS; Safety and tolerability

Select inclusion criteria

- Age ≥18
- Diagnosis of PMF, PPV-MF, or PET-MF
- DIPSS risk category of intermediate-1, intermediate-2, or high
- Ruxolitinib treatment ≥ 3 months with stable dose for ≥ last 8 weeks prior to Day 1
- Suboptimal response to Ruxolitinib as defined by palpable spleen ≥ 5 cm BLCM and TSS ≥ 10
- Platelets ≥50 x 10^9/L

Select exclusion criteria

- Prior therapy with any PI3K inhibitor
- Prior use of experimental drug therapy for MF or any other standard drug used for MF, except Ruxolitinib, within 3 months of starting study drug, and/or lack of recovery from all toxicities from previous therapy (except Ruxolitinib) to Grade 1 or better
- Recent history of inadequate bone marrow reserve
- Inadequate liver and renal function at screening
- Splenic irradiation within 6 months of 1st study drug

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] Parsaclisib

BID: Twice a day; BLCM: below left costal margin; DIPSS: Dynamic International Prognostic Scoring System; MF: Myelofibrosis; OS: Overall Survival; PET: Post Essential Thrombocythemia; PI3K: Phosphoinositide-3-kinase; PMF: Primary MF; PO: Peroral; PPV: Post Polycythemia Vera; Prim. Compl.: Primary completion; QD: Once daily; TSS: Total Symptom Score.

https://clinicaltrials.gov/ct2/show/NCT04551053, Accessed 08 March,2021

DE/TAFACD19/NP/21/0014, 25 March 2021