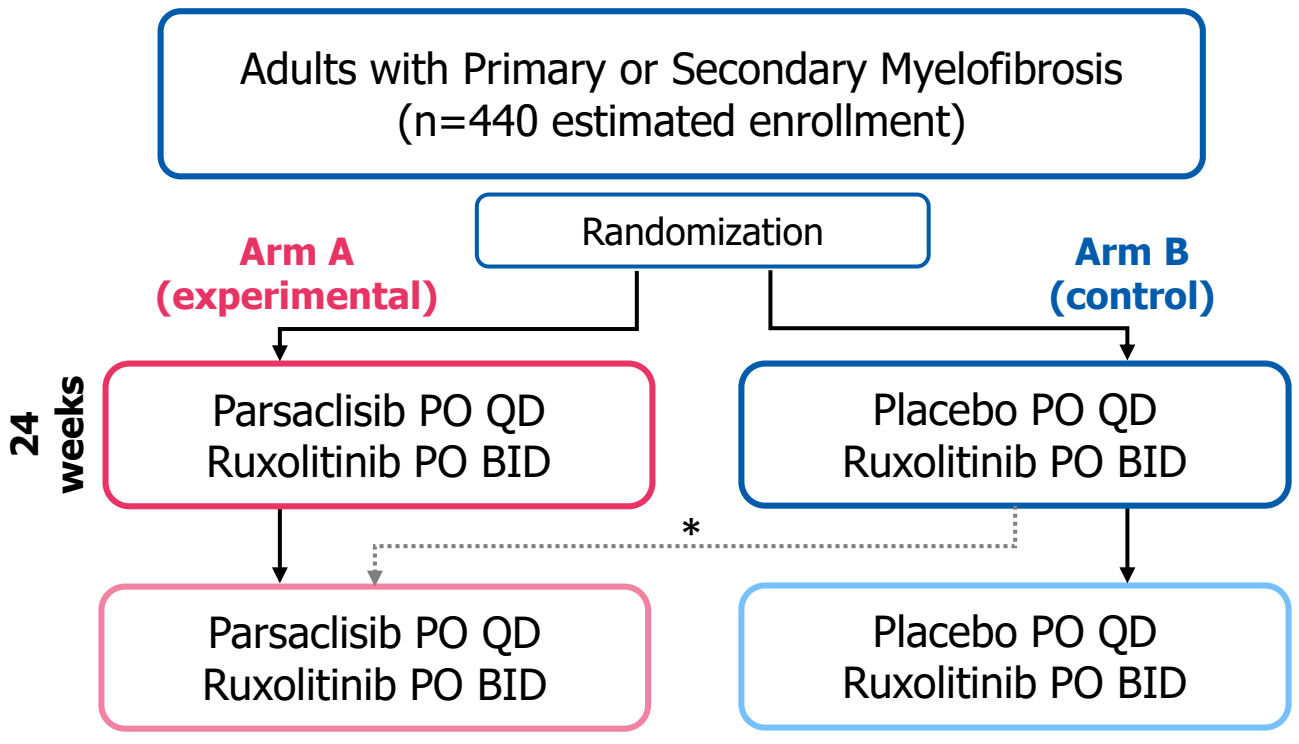
LIMBER

LEADING IN MPNS BEYOND RUXOLITINIB

NCT04551066 | Phase 3 | Myelofibrosis

Incyte

Double-blind, Placebo-controlled, randomized study evaluating Ruxolitinib in combination with Parsaclisib (PI3Kδ inhibitor) in participants with Myelofibrosis



* Crossover allowed after last patient finishes 24 weeks

Primary end point

- Spleen volume reduction (baseline to 24 weeks)

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 of targeted reduction of spleen volume
- Duration of maintenance of targeted spleen volume reduction
- 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
- Palpable spleen ≥ 5 cm BLCM and TSS ≥ 10
- Platelets ≥50 x 10^9/L
- ECOG PS 0-2

Select exclusion criteria

- Prior therapy with any JAK or PI3K inhibitor
- Prior use of experimental drug therapy for MF or any other standard drug used for MF within 3 months of starting study drug, and/or lack of recovery from all toxicities from previous therapy to ≤ Grade 1
- 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; ECOG: Eastern Cooperative Oncology Group Performance Status; JAK: Janus Kinase; MF: Myelofibrosis; PET: Post Essential Thrombocythemia; PI3K: Phosphoinositide-3-kinase; PMF: Primary MF; PO: Peroral; PPV: Post Polycythemia Vera; Prim. Compl.: Primary completion; OS: Overall Survival; QD: Once daily; TSS: Total Symptom Score. https://clinicaltrials.gov/ct2/show/NCT04551066, Accessed 12 March,2021

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