

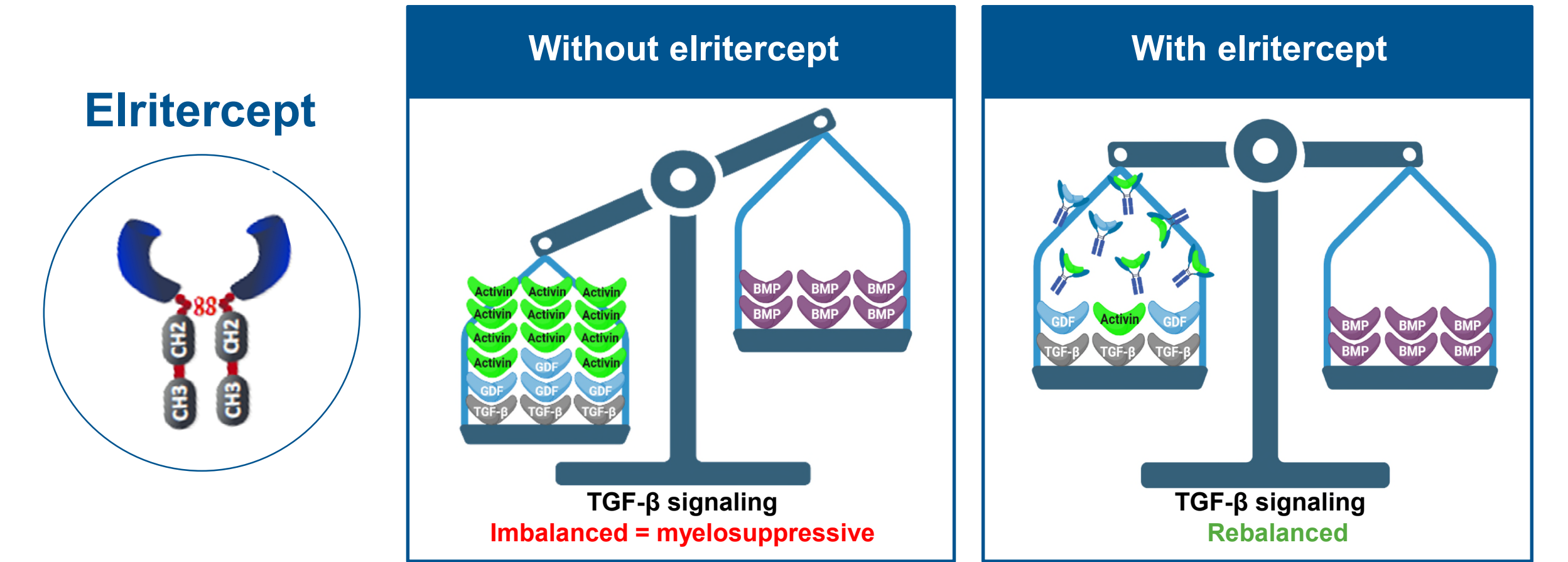
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Background and elritercept mechanism of action

- Anemia is common in patients with MF, and is associated with fatigue, transfusion dependence (TD), reduced health-related quality of life (HRQoL), and shortened survival^{1,2}
- Janus kinase (JAK) inhibitors such as ruxolitinib are a standard of care treatment option for MF, but are associated with cytopenias and anemia exacerbation, which can lead to suboptimal dosing due to dose interruptions or reductions^{1,3}
- There is an unmet need for new therapy options that address disease- and treatment-related anemia for patients with MF¹ that could reduce TD and improve HRQoL and survival outcomes
- Elritercept is an investigational TGF-β superfamily ligand trap designed to block activin A/B and growth differentiation factor 8/11, and restore effective hematopoiesis beyond erythroid maturation⁴ (**Figure 1**)
- In the phase 2 RESTORE study (NCT05037760), elritercept (alone and in combination with ruxolitinib) was well-tolerated and demonstrated clinically meaningful improvements in anemia, transfusion burden, splenomegaly, and MF symptoms, suggesting disease modifying potential^{5,6}

Figure 1: Elritercept proposed mechanism of action



BMP, bone morphogenic protein; CH2/3, constant heavy-chain domain 2/3; TGF-β, transforming growth factor β.

Study design

- This randomized, double-blind, placebo-controlled, phase 3 study (NCT07623161) will evaluate the efficacy and safety of elritercept in patients with MF and TD-anemia on background ruxolitinib therapy (**Summary Panel**)
- The study will consist of an initial 36-week double-blind treatment phase, followed by an extended open-label treatment phase, and a subsequent post-treatment follow-up phase
- Patients will be randomized 1:1 to receive elritercept 3.75 mg/kg, subcutaneously (SC), once every four weeks (Q4W), or matching placebo, both in combination with ruxolitinib in accordance with locally approved prescribing information
 - Starting at Cycle 3, Day 1, patients will be assessed for up-titration of study treatment to 5 mg/kg after receiving two consecutive doses at the same dose level and without interruption, as deemed appropriate by study investigators, to maintain hemoglobin (Hgb) levels (females: 10–12 g/dL; males: 11–13 g/dL)
- At the end of the 36-week double-blind treatment phase, patients in the placebo arm will be given the option to cross over to elritercept 3.75 mg/kg SC, Q4W, combined with ongoing ruxolitinib

References

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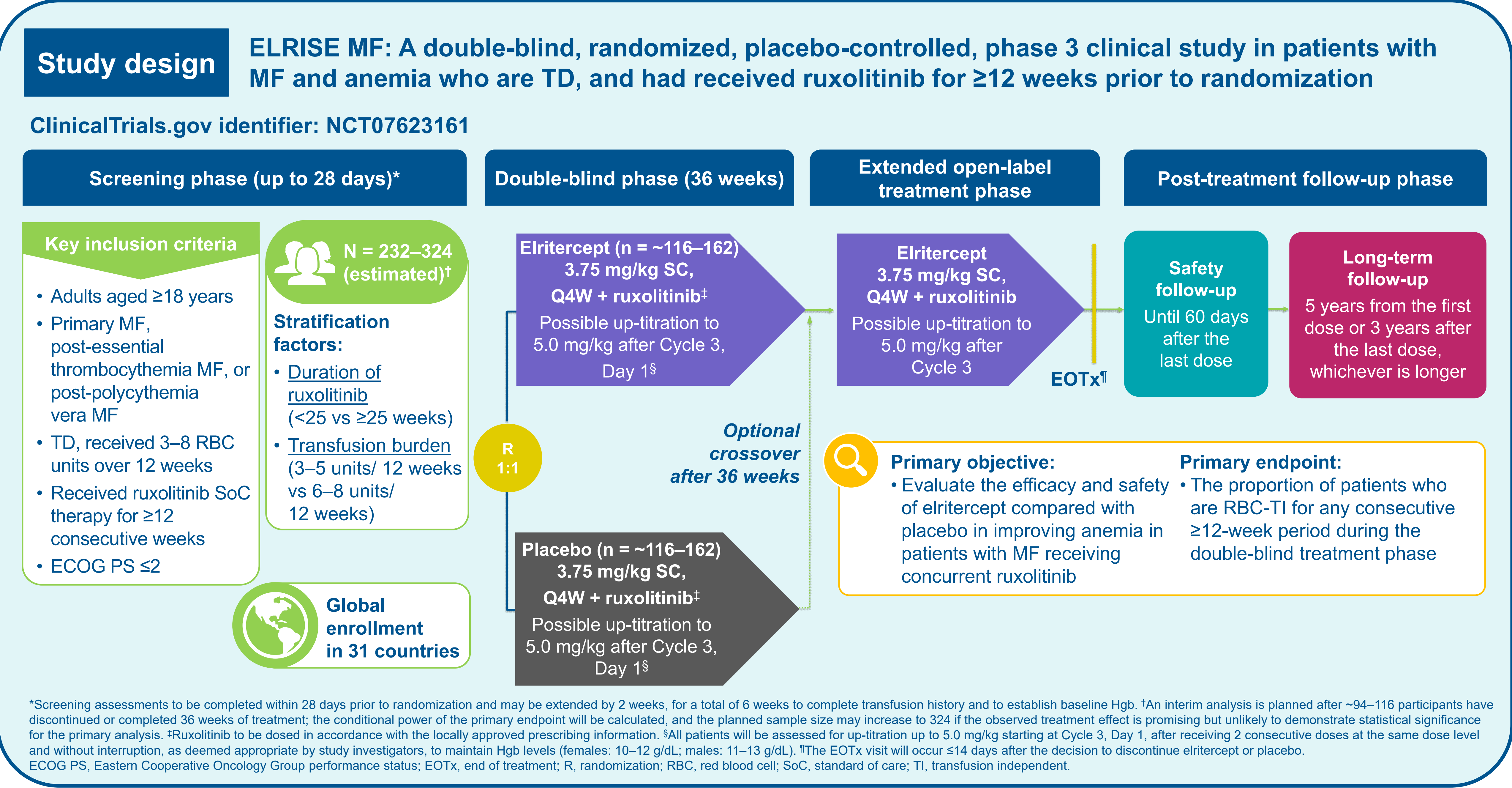
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Disclosures

PB: advisory council or committee participation for Karyopharm, Sumitomo, GSK, Takeda, PharmaEssentia, Geron, Novartis, and RayThera; honoraria from Incyte, Sumitomo, GSK, Sobi, AbbVie, PharmaEssentia, Disc Medicine, Karyopharm, and Novartis; consulting fees from Incyte, Bristol Myers Squibb (BMS), Sobi, GSK, Novartis, Takeda, Merck, Cogent Biosciences, Blueprint Medicines, Ionis, Deciphera, Disc Medicine, PharmaEssentia, AbbVie, Karyopharm, Jubilant, Morphic, VYNE Therapeutics, V6 Therapeutics, and Damora Therapeutics; and grants or funding from Incyte, BMS, GSK, Merck, Novartis, Kartos Therapeutics, Telios Pharma, Ionis, Disc Medicine, Sumitomo, Karyopharm, Cogent Biosciences, Blueprint Medicines, Ajax Therapeutics, Geron, and Janssen.

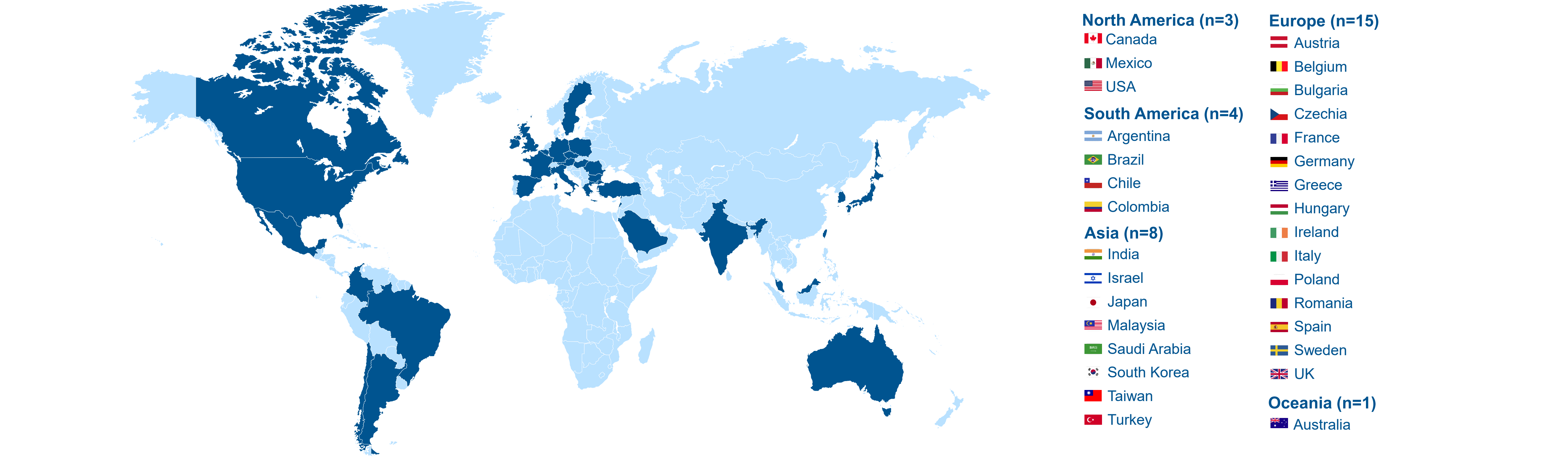
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Enrollment and study locations

- Approximately 232–324 patients will be enrolled in the study, from 199 sites across 31 countries in North America, South America, Asia, Europe, and Oceania (**Figure 2**)

Figure 2: Map of the planned study sites across the globe



Patient eligibility

- The inclusion criteria are listed in the **Summary Panel**

Key exclusion criteria

- Prior treatment with lusatercept, sotatercept, or other TGF-β inhibitors or activin receptor ligand traps
- Systemic treatment with any of the following within 28 days before randomization:
 - Hematopoietic growth factors
 - Androgens
 - High-dose corticosteroids
 - Cytoreductive agents
 - Immunomodulatory drugs
 - Interferon
 - Thrombopoietin receptor agonists
- Clinically significant anemia due to any cause other than MF or JAK inhibitor therapy
- Receipt of RBC transfusion for any reason other than MF within 12 weeks before randomization
- Life expectancy <12 months

Objectives		Endpoints	
Primary			
Secondary			

[†]Anemia response is evaluated using multiple definitions: achievement of RBC-TI for any consecutive ≥12-week, ≥16-week, or ≥24-week period, or ≥50% reduction in RBC transfusion burden from baseline over any consecutive 12 weeks. Time to onset of anemia response is defined as the duration between the date of randomization and the date that patients first achieve anemia response. EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; MFSAF, Myelofibrosis Symptom Assessment Form; PROMIS, Patient-Reported Outcomes Measurement Information System; TSS, Total Symptom Score.

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