MOMENTUM
MYELOFIBROSIS CLINICAL TRIAL

A Randomized, Double-Blind, Phase 3 Study to Evaluate the Activity of Momelotinib (MMB) versus Danazol (DAN) in Symptomatic, Anemic Subjects with Primary Myelofibrosis (PMF), Post-Polycythemia Vera (PV) Myelofibrosis, or Post Essential Thrombocythemia (ET) Myelofibrosis who were Previously Treated with JAK Inhibitor Therapy.

Rationale

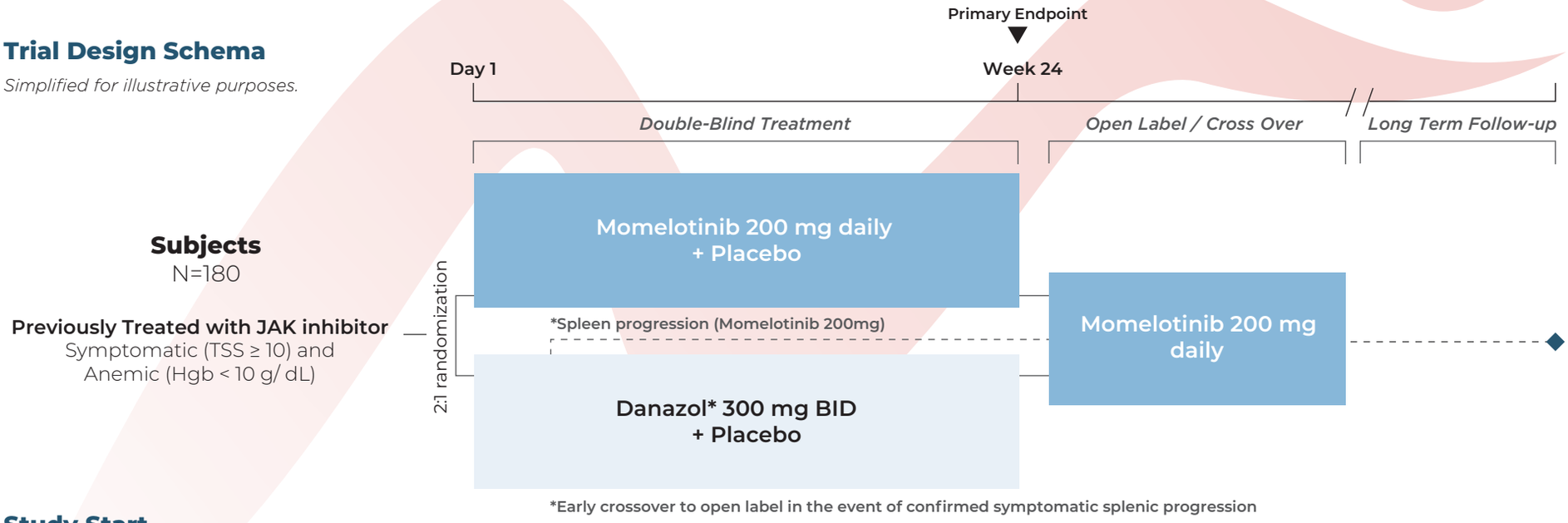
There exists a high unmet need for new treatment options for symptomatic and anemic patients who have previously been treated with an approved JAK inhibitor. This study aims to determine the activity of momelotinib on the key disease manifestations of myelofibrosis including symptomatology, anemia, and splenomegaly.

Investigational Agent

Momelotinib (MMB) is a potent, selective, small-molecule inhibitor of Janus kinase 1 (JAK1), Janus kinase 2 (JAK2) and activin A receptor type 1 (ACVR1). MMB is currently under development by Sierra Oncology for the treatment of myelofibrosis.

Trial Design Schema

Simplified for illustrative purposes.



Study Start

Trial launched in Q4 2019.

Rationale for Comparator Arm

Danazol has been selected as an appropriate treatment comparator given its use to ameliorate anemia in myelofibrosis patients, as recommended by NCCN and ESMO guidelines (NCCN, 2018; Vannucchi, 2015).

Momelotinib is an investigational agent not yet approved by the US FDA or any regulatory authority

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Selected Study Endpoints

Primary:

- Total symptom score (TSS) response rate of MMB vs DAN at Week 24 in symptomatic and anemic patients with PMF, post-PV myelofibrosis, or post-ET myelofibrosis who were previously treated with an approved JAK inhibitor therapy.

Secondary:

- Transfusion independence (TI) rate at Week 24 for subjects treated with MMB vs DAN.
- Splenic response rate (SRR) at Week 24 for subjects treated with MMB vs DAN.
- Duration of TSS response for subjects treated with MMB.
- Other measures of anemia benefit, including TD-TI rate and measures of cumulative transfusion burden.
- Additional patient reported outcomes, including assessments of fatigue and physical function.

Key Inclusion Criteria

- High risk, intermediate-2, or intermediate-1 risk as defined by Dynamic International Prognostic Scoring System (DIPSS), or DIPSS-plus.
- Symptomatic - TSS of ≥ 10 units assessed by MFSAF.
- Anemic - hemoglobin (Hgb) < 10 g/dL.
- Previously treated with an approved JAK inhibitor for PMF or Post-PV/ET myelofibrosis for ≥ 90 days, or ≥ 28 days if JAK inhibitor therapy is complicated by RBC transfusion requirement of ≥ 4 units in 8 weeks, or Grade 3/4 thrombocytopenia, anemia, or hematoma.
- Splenomegaly that is palpable ≥ 5 cm below the left costal margin, or with a volume ≥ 450 cm^3.
- Platelets ≥ 25 x 10^9/L, neutrophils ≥ 0.75 x 10^9/L and peripheral blast count < 10%.
- No allogeneic stem cell transplant planned.

Chief Investigators

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