Study of Navtemadlin add-on to Ruxolitinib in JAK Inhibitor-Naïve Patients With Myelofibrosis Who Have a Suboptimal Response to Ruxolitinib

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria for Ruxolitinib Alone Period: * Confirmed diagnosis of PMF, post-PV MF, or post-ET MF, as assessed by the treating physician according to the World Health Organization (WHO) criteria * High, Intermediate-1, Intermediate-2 risk category International Prognosis System Score (IPSS) * Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 * JAK-inhibitor treatment naive Exclusion Criteria for Ruxolitinib Alone Period: * Prior Splenectomy * Splenic irradiation within 3 months prior to the first dose * Prior BCL-XL, BET, MDM2, PI3K, PIM, or XPO1 inhibitors therapy or p53-directed therapy * Eligible for Bone Marrow Transplant * Peripheral blood or bone marrow blast count ≥ 10 percent Inclusion Criteria for Randomized Period: * PMF, post-PV MF, or post-ET MF that is TP53WT as assessed by central testing * ECOG performance status of 0 to 2 * Treatment with a stable dose of ruxolitinib * Suboptimal response to run-in ruxolitinib treatment Exclusion Criteria for Randomized Period: * Elevated white blood cell count that doubles (or more) during ruxolitinib treatment and exceeds 50 × 10\^9/L * Peripheral blood or bone marrow blast count ≥ 10 percent

Conditions & Interventions

Interventions:

DRUG: Navtemadlin, DRUG: Navtemadlin placebo, DRUG: Ruxolitinib

Conditions:

Myelofibrosis, Post-PV MF, Post-ET Myelofibrosis, Primary Myelofibrosis, MF

Keywords:

Navtemadlin, KRT-232, Ruxolitinib, POIESIS, TP53, Suboptimal response, Sub-optimal response

More Information

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Phase: PHASE3

IRB

Number:

System ID: NCT06479135
