

A complete listing of sites and additional information for this clinical trial can be found at clinicaltrials.gov/study/NCT07429266.



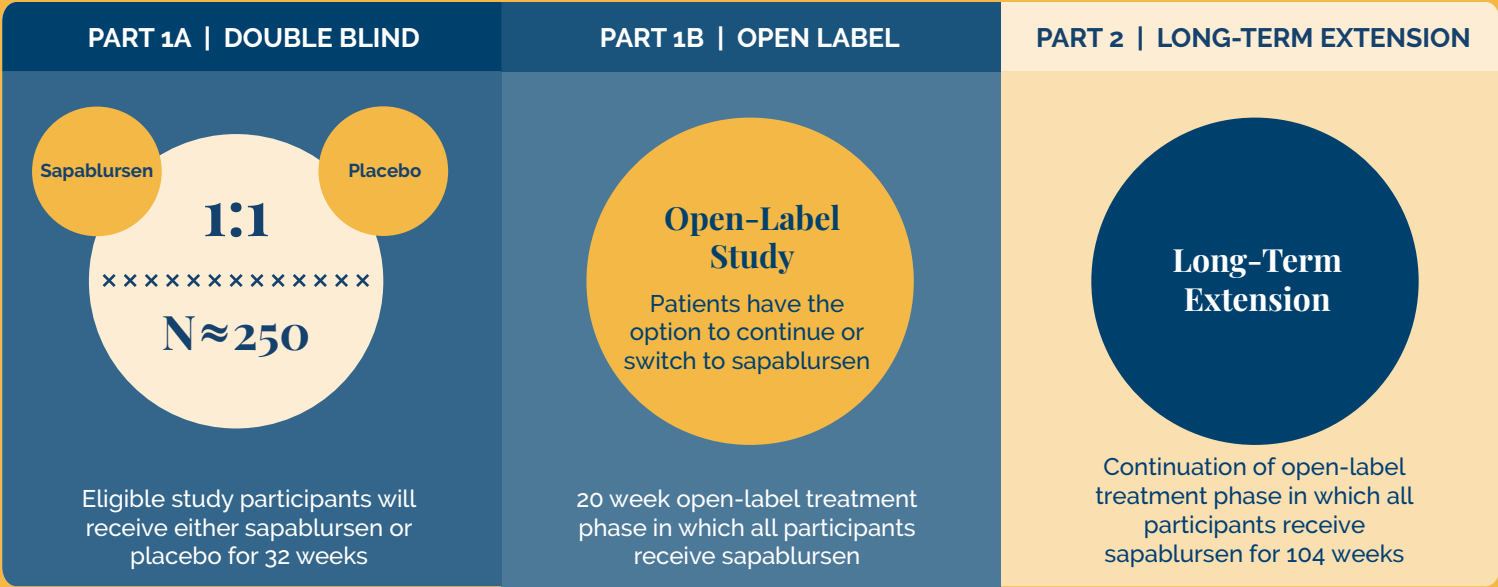
For more information, email
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Sapablursen

INTREPID: A Phase 3, Randomized, Double-blind, Placebo-controlled Global Study of Sapablursen in Polycythemia Vera (PV)

Study Design

A Phase 3 randomized, double-blind placebo-controlled, global study to evaluate the efficacy and safety of sapablursen when added to current PV therapy in patients with phlebotomy-dependent PV



Primary Outcome Measure

- Percentage of participants with absence of phlebotomy eligibility

Secondary Outcome Measures

- Number of phlebotomies
- Percentage of participants with Hct control
- Change from baseline in Patient Reported Outcomes Measurement Information System (PROMIS) Fatigue Short Form Total T-score
- Change from baseline in Myelofibrosis Symptom Assessment Form (MFSAF) Total Symptom Score (TSS)

Select Inclusion Criteria

- Meet revised 2022 World Health Organization (WHO) and 2022 International Consensus Classification criteria for the diagnosis of PV
- Participants must be phlebotomy-dependent
- Hct less than (<) 45% at study start
- Participants receiving Cyto-reduction therapy (CRT) must be on a stable regimen at study start
- Adequate organ function and electrolytes

Select Exclusion Criteria

- Prior treatment of PV with Transmembrane serine protease 6 (TMPRSS6) inhibitors, including sapablursen, or hepcidin mimetics
- Clinically significant thrombosis (eg, myocardial infarction, stroke, deep vein thrombosis or splenic vein thrombosis) within 1 month prior to randomization
- Participants who require phlebotomy at Hct levels <45%
- Meet the criteria for post-PV myelofibrosis as defined by the International Working Group-Myeloproliferative Neoplasms Research and Treatment (IWG-MRT)
- Any serious or unstable medical condition or uncontrolled psychiatric condition that would interfere with their ability to comply with study requirements

Abbreviations: Hct=hematocrit; PV=polycythemia vera

Sapablursen is an investigational antisense oligonucleotide therapy designed to treat polycythemia vera (PV) by inhibiting the TMPRSS6 gene. Sapablursen is an investigational drug that has not been approved by the US FDA, European Commission, or any other regulatory agency.