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A complete listing of sites and additional information for this clinical trial can be found at **clinicaltrials.gov/study/NCT06619561**.

For more information, email
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Vimseltinib

A Phase 2, Open-Label, Multicenter Study to Evaluate the Safety, Tolerability, PK, and Efficacy of Vimseltinib in Adults with Active Chronic GVHD After Failure of Prior Systemic Therapy

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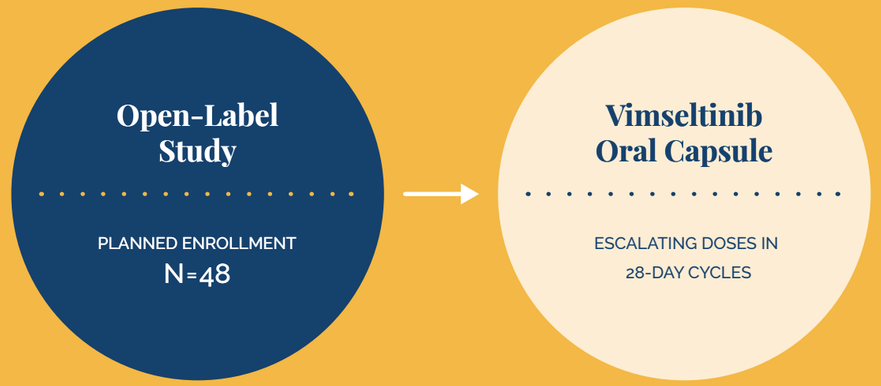
The study described here is an investigational study of vimseltinib. Vimseltinib is not approved or indicated for patients with active chronic graft-versus-host disease by the US FDA, European Commission, or any other regulatory agency.

Study Design

Phase 2, dose escalation, open-label study of vimseltinib for treatment of adults with active moderate to severe cGVHD after failure of prior systemic therapy



Primary Outcome Measures

- Number of participants with dose-limiting toxicities
- Number of participants with adverse events and serious adverse events

Secondary Outcome Measures

- Objective response rate (ORR)
- Duration of response (DOR)
- Organ-specific response
- Failure-free survival (FFS)
- Pharmacokinetics (PK): Maximum Observed Plasma Concentration (Cmax)

Select Inclusion Criteria

- Must be allogeneic hematopoietic stem cell transplant (HSCT) recipients with moderate to severe cGVHD requiring systemic immune suppression
  - May have persistent aGVHD and cGVHD manifestations (overlap syndrome)
- Received and failed at least 2 prior lines of systemic therapy
- If taken systemic corticosteroids, be on a stable dose for at least 2 weeks prior to starting study drug treatment
- Adequate organ and bone marrow functions
- Participants of reproductive potential agree to follow contraception requirements
- Karnofsky Performance Scale (KPS) of ≥60

Select Exclusion Criteria

- Has aGVHD without manifestations of cGVHD
- Prior use of CSF1R inhibitor for cGVHD
- History or evidence of severe illness, uncontrolled infection, or conditions making participant unsuitable for the study
- History of malignancy except for:
  - Underlying malignancy for which the transplant was performed
  - Malignancy treated with curative intent and with no evidence of active disease present for more than 3 years prior to enrollment and felt to be at low risk for recurrence
- Malabsorption syndrome or illness that could affect oral absorption

Abbreviations: aGVHD=acute Graft-Versus- Host Disease; cGVHD=chronic Graft-Versus- Host Disease; CSF1R=colony-stimulating factor 1 receptor

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