

Ruxolitinib Plus Fostamatinib for Steroid Refractory cGvHD

NCT06233110

Status	RECRUITING
Phase	Phase 1
Sponsor	Stefanie Sarantopoulos, MD, PhD.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (9)

- Patient is able and willing to provide written informed consent prior to any study related screening procedures are performed.
- Age e 18 years old at the time of informed consent
- Have undergone allogeneic hematopoietic cell transplantation (HCT) from any donor source (matched unrelated donor, sibling, haploidentical) using bone marrow, peripheral blood, or cord blood stem cells.
- Adequate bone marrow function defined as:
- Absolute neutrophil count (ANC) e 750 /mm³ 4.2 Platelet count e 40,000 /mm³ 4.3 Hemoglobin e 8.0 g/dL without transfusion support Note: Use of growth factor supplementation (myeloid, erythroid or megakaryocytic) is permitted to meet eligibility criteria.
- ... and 4 more (see full listing online)

Exclusion (16)

- Prior or ongoing treatment with ruxolitinib for treatment of cGvHD for longer than 3 weeks prior to anticipated C1D1.
- Prior treatment with fostamatinib or another SYK inhibitor for the treatment of acute or chronic GVHD. Prior use of fostamatinib for conditions other than GVHD is permitted.
- Ongoing systemic therapy for cGvHD other than corticosteroids, calcineurin inhibitor, or mycophenolate mofetil, aside from fewer than 3 weeks of ruxolitinib. Prior ruxolitinib use for the indication of acute GVHD is permitted.
- Patients with relapsed primary malignancy, or who have been treated for relapse after the allogeneic HCT was performed
- SR-cGvHD occurring after a non-scheduled donor lymphocyte infusion (DLI) administered for pre-emptive treatment of malignancy recurrence. Patients who have received a scheduled DLI as part of their transplant procedure and not for management of malignancy relapse are eligible.
- ... and 11 more (see full listing online)

Locations (1 total)

Duke, Durham, North Carolina, United States

<https://clinicaltrials.gov/study/NCT06233110>

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