

# Axatilimab in Combination With Extracorporeal Photopheresis (ECP) in Chronic Graft-versus-Host Disease

NCT06663722

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Status	RECRUITING
Phase	Phase 2
Sponsor	University of Miami
Enrollment	49 participants

## Key Eligibility Criteria

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### Inclusion (16)

- Recipient of allogeneic hematopoietic cell transplantation (HCT).
- Age greater or equal to 12.
- Chronic GVHD per 2014 National Institutes of Health Consensus Criteria (NCC) (Jagasia et al. 2015) or overlap syndrome requiring new therapy in patients with at least 2 prior lines of therapy, steroid refractoriness, or steroid dependence:
- Prior systemic lines of therapy may include corticosteroids, calcineurin inhibitor (CNI) or sirolimus, or other systemic immunosuppressive agent such as ruxolitinib, belumosudil, or ibrutinib. GVHD prophylaxis does not count as a prior line of therapy.
- Steroid refractory is defined as any of the following criteria:

... and 11 more (see full listing online)

### Exclusion (17)

- Pregnancy or breast-feeding.
- Active relapse of underlying malignancy.
- History or the presence of interstitial pneumonitis or drug-related pneumonitis.
- Active gastrointestinal (GI) bleeding.
- Inability to tolerate volume shifts associated with ECP (e.g., inadequate renal, hepatic, pulmonary and cardiac function (ejection fraction (EF)  $\lt$  40%) per Investigator discretion.

... and 12 more (see full listing online)

## Locations (1 total)

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University of Miami, Miami, Florida, United States