

Steroid-Sparing Strategies in Chronic Graft-Versus-Host Disease (cGVHD): Can Early Combination Therapy Improve Frontline Outcomes?

Phase 2 Axatilimab + Ruxolitinib Trial (NCT06388564)¹

Systemic corticosteroid therapy is the first-line treatment for patients who develop moderate or severe steroid-refractory chronic GVHD (SR-cGVHD)²

Due to their potent anti-inflammatory and immunosuppressive effects, corticosteroids have been the initial choice of therapy for patients who develop GVHD.³

For patients who develop cGVHD, however, corticosteroid therapy has significant adverse effects that lead to worsening quality of life and increased non-relapse mortality.²

Given the long list of comorbidities, there continues to be significant interest in investigating alternative therapies that can more effectively target the underlying immune dysregulation and inflammatory response.²

Combination therapy using ruxolitinib and axatilimab is being explored as a promising way to address this gap in patients with newly diagnosed cGVHD.¹⁻³

A Phase 2, Open-Label, Randomized, Multicenter Study to Evaluate the Safety and Efficacy of Axatilimab in Combination With Ruxolitinib in Participants With Newly Diagnosed Chronic Graft-Versus-Host Disease¹

GLOBAL STUDY
70
Locations
across US,
Canada, & EU

Select Participation Criteria¹

- ≥ 12 years of age
- New onset moderate or severe cGVHD, as defined by 2014 the National Institutes of Health Consensus Development Project
- History of 1 allogeneic stem cell transplant
- No previous systemic steroid or other targeted therapy for cGVHD
- No history of: acute or chronic pancreatitis, thromboembolic events in the 6 months prior to study entry, active symptomatic myositis, severe renal impairment, impaired liver function, and active significant cardiac disease

N = 120
Newly
diagnosed
patients
with cGVHD



- Axatilimab + ruxolitinib
- Ruxolitinib
- Corticosteroids

Study
Start Date:
10-11-2024

Estimated Study
Completion Date:
12-01-2029

Primary Outcome Measure:
The objective response rate at 6 months in the absence of new systemic therapy for cGVHD¹

References

1. Study to evaluate the safety and efficacy of axatilimab in combination with ruxolitinib in participants with newly diagnosed chronic graft-versus-host disease. ClinicalTrials.gov identifier: NCT06388564. Accessed August 28, 2025. <https://clinicaltrials.gov/study/NCT06388564>

2. Zeiser R, et al. Ruxolitinib for glucocorticoid-refractory chronic graft-versus-host disease. *NEJM*. 2021;385:228-238. doi: 10.1056/NEJMoa2033122

3. Hill L, et al. New and emerging therapies for acute and chronic graft versus host disease. *Ther Adv Hematol*. 2018; 9(1): 21–46. doi: 10.1177/2040620717741860

