Comparative Efficacy of Nipocalimab and Efgartigimod in Participants With Generalized Myasthenia Gravis

NCT07217587

Status	RECRUITING
Phase	Phase 3
Sponsor	Janssen Research & Development, LLC
Enrollment	115 participants

Key Eligibility Criteria

Inclusion (8)

- For all arms:
- Medically stable on the basis of physical examination, medical history, vital signs, clinical laboratory tests, and 12-lead electrocardiogram (ECG) performed at screening
- Diagnosis of myasthenia gravis (MG) with generalized muscle weakness meeting the clinical criteria for generalized MG (gMG) as defined by the Myasthenia gravis foundation of America (MGFA) clinical classification class II a/b, III a/b, or IV a/b at screening and positive for acetylcholine receptor (AChR) antibodies
- Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of greater than or equal to (\>=) 5 with less than (\<) 50% of symptoms coming from ocular MG-ADL sub-scores at study screening and baseline (Day 1) visits
- Criteria specific to Arms 1 and 2 only:

... and 3 more (see full listing online)

Exclusion (7)

- Any confirmed or suspected clinical immunodeficiency syndrome not related to treatment of his/her gMG, or has a family history of congenital or hereditary immunodeficiency unless confirmed absent in the participant
- Had a thymectomy within 1 year prior to baseline, or thymectomy is planned during the study
- Currently has a malignancy or has a history of malignancy within 3 years before baseline
- Criteria specific to Arms 1 and 2 only:
- \- Has received treatment for MG with an FcRn-targeting therapy

... and 2 more (see full listing online)

Locations (7 total)

University of Connecticut, Farmington, Connecticut, United States
SFM Clinical Research LLC, Boca Raton, Florida, United States
HSHS St. Elizabeth's Hospital, O'Fallon, Illinois, United States
... and 4 more locations

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