A Study to Compare TAK-881 and HYQVIA in Adults With Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)

NCT06747351

Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	59 participants

Key Eligibility Criteria

Inclusion (11)

- Participant is willing and able to understand and fully comply with trial procedures and requirements, in the opinion of the investigator.
- Participant has provided informed consent (that is, in writing, documented via a signed and dated informed consent Form \[ICF\]) and any required privacy authorization before the initiation of any trial procedures.
- Participant has a documented diagnosis of CIDP or possible CIDP, as confirmed by a neurologist specializing/experienced in neuromuscular diseases and consistent with the European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS) 2021 criteria.
- Participant has responded to IgG treatment in the past (documented partial or complete resolution of neurological symptoms and deficits).
- Participant is on a stable, pretrial treatment with IGIV, cIGSC, or HYQVIA (also known as TAK-771 in Japan) within the dose range equivalent to a cumulative monthly IgG dose of 0.4 to 2.4 grams per kilogram (g/kg) body weight (BW) (inclusive) administered for at least 12 weeks before screening. The dosing interval of IGIV treatment must be between 2 and 6 weeks (inclusive). The dosing interval must be weekly or biweekly for cIGSC dosing and less than or equal (\<=) to 6 weeks for HYQVIA dosing. Prior to screening, variations in the dosing interval of up to +-7 days or monthly dose amount of up to +-20 percentage (%) between the participant's pretrial IgG infusions are acceptable.

... and 6 more (see full listing online)

Exclusion (35)

- Participant with documented diagnosis of focal, multifocal, distal, or sensory CIDP, or possible focal, multifocal, distal, or sensory CIDP per the EFNS/PNS 2021 criteria.
- Participant has any neuropathy of other causes, including:
- Hereditary demyelinating neuropathies, such as hereditary sensory and motor neuropathy (HSMN), Charcot-Marie-Tooth (CMT) disease, and hereditary sensory and autonomic neuropathies (HSANs).
- Neuropathies secondary to infections, disorders, or systemic diseases such as Borrelia burgdorferi infection (Lyme disease), diphtheria, systemic lupus erythematosus, POEMS (polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes) syndrome, osteosclerotic myeloma, diabetic and non-diabetic lumbosacral radiculoplexus neuropathy, lymphoma, amyloidosis.
- Multifocal motor neuropathy (MMN).

... and 30 more (see full listing online)

Locations (52 total)

HonorHealth Neurology, Scottsdale, Arizona, United States
Stanford Neuroscience Health Center, Palo Alto, California, United States
Yale University School of Medicine, New Haven, Connecticut, United States
... and 49 more locations