A Study to Learn More About the Effects and Safety of Felzartamab Infusions in Adults With Primary Membranous Nephropathy (PMN)

NCT06962800

Status	RECRUITING
Phase	Phase 3
Sponsor	Biogen
Enrollment	180 participants

Key Eligibility Criteria

Inclusion (7)

- Diagnosed with PMN in need of IST according to the Investigator's clinical judgment. The diagnosis of PMN must be documented with the presence of nephrotic syndrome, and hypoalbuminemia, and confirmed with a kidney biopsy either during Screening or within 5 years of signing the informed consent form (ICF) \[see kidney biopsy exception below for participants positive for anti-PLA2R antibodies\]. For these participants, the biopsy report with redacted protected health information must be available to be reviewed by the Sponsor or an independent nephropathologist. If the participant requires a kidney biopsy during Screening, medical monitor approval must be obtained and all other eligibility criteria should be reviewed to ensure that the participant is otherwise eligible prior to performing the kidney biopsy.
- a. Kidney biopsy exception for anti-PLA2R antibody positive participants: Participants who are positive for anti-PLA2R antibodies and have not had a kidney biopsy performed within 5 years of signing the ICF, may be eligible for the study without undergoing a kidney biopsy based on medical monitor review confirming normal estimated glomerular filtration rate (eGFR), presence of nephrotic syndrome, hypoalbuminemia, positive anti-PLA2R antibody test (defined as an anti-PLA2R antibody titer \> 20 RU/mL), and documentation provided by the Investigator that the work-up for secondary causes of membranous nephropathy (MN) was negative with no identifiable secondary causes.
- Meets one of the following:
- Newly diagnosed PMN, defined as having never received IST for PMN in the past.
- Relapsed PMN, defined as documented achievement of CR or partial remission (PR) after treatment with an IST for PMN followed by reappearance of nephrotic range proteinuria (urine protein to creatinine ratio \[UPCR\] e 3.0 gram per gram \[g/g\] from a 24-hour urine collection or proteinuria e 3.5 gram per 24 hour \[g/24 h\]).

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

Exclusion (2)

- Secondary cause of MN (e.g., malignancies, medications, systemic lupus erythematosus \[SLE\], hepatitis B, hepatitis C, etc).
- Severe renal impairment defined as an eGFR d 30 mL/min/1.73m\^2 at Screening or including the need for dialysis or renal replacement therapy.

Locations (85 total)

Apogee Clinical Research, LLC, Huntsville, Alabama, United States
The Nephrology Group, Inc. - Fresno, Fresno, California, United States
Academic Medical Research Institute, Los Angeles, California, United States
... and 82 more locations