A Study to Learn About the Effects of Felzartamab Infusions on Adults With Immunoglobulin A Nephropathy (IgAN)

NCT06935357

Status	RECRUITING
Phase	Phase 3
Sponsor	Biogen
Enrollment	454 participants

Key Eligibility Criteria

Inclusion (4)

- Biopsy-confirmed diagnosis of IgAN within the past 10 years prior to signature of the informed consent form (ICF). For participants with diabetes mellitus type 2, biopsy confirmation of IgAN diagnosis must be done within the past 24 months prior to signing the ICF.
- An eGFR e 30 mL/min/1.73m\^2 at Screening as calculated using the 2021 chronic kidney disease epidemiology (CKD-EPI) creatinine formula. An eGFR of e 20 and \< 30 mL/min/1.73m\^2 is acceptable for the cohorts 3 and 4.
- Proteinuria of e 1.0 gram per day (g/day) or UPCR e0.8 gram per gram (g/g) as assessed by an adequate 24-hour urine collection.
- Clinically stable on a maximally tolerated dose or maximally approved dose of angiotensin-converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) for at least 12 weeks prior to Screening, or intolerant of ACEI or ARB. If intolerant, this must be discussed with the Medical Monitor prior to randomization. Participants may also be using sodium-glucose cotransporter-2 inhibitors (SGLT2is), endothelin receptor antagonists (ERAs) approved for the treatment of IgAN, dual endothelin angiotensin receptor antagonist (DEARAs) approved for the treatment of IgAN, and/or mineralocorticoid receptor antagonists (MRAs) as long as the dose is stable for at least 12 weeks prior to Screening. Participants should remain on stable doses of these background medications for the duration of the study. Once the ICF is signed and thereafter, the doses cannot be changed during the study nor the drugs discontinued except if deemed related to an AE. Participants using sparsentan will not be permitted to use simultaneous ACEI or ARB medication.

Exclusion (10)

- Secondary forms of IgAN, indicated by the presence of any other systemic disease potentially leading to IgA deposits as determined by the Investigator.
- History of rapidly progressive variant of IgAN, defined as eGFR loss by \> 50% per 3 months and not explained by changes in renin-angiotensin system (RAS) blockade or other factors.
- Nephrotic syndrome presumed to be due to minimal change disease (MCD) variant.
- Concomitant other progressive glomerulonephritis or non-immunologic glomerular disease such as diabetic nephropathy.
- Type 2 diabetes mellitus with Hemoglobin A1c (HbA1c) \> 8% at Screening, or evidence of diabetic nephropathy on biopsy, history of diabetic microvascular or macrovascular disease (eg, diabetic retinopathy, peripheral neuropathy).

... and 5 more (see full listing online)

Locations (215 total)

Applied Research Center of Arkansas, Little Rock, Arkansas, United States
Kidney & Hypertension Center - Apple Valley, Apple Valley, California, United States
Scripps Green Hospital, Carlsbad, California, United States
... and 212 more locations