A Study to Assess the Effects of Zigakibart on IgA Nephropathy.

NCT07146906

Status	RECRUITING
Phase	Phase 2
Sponsor	Novartis Pharmaceuticals
Enrollment	32 participants

Key Eligibility Criteria

Inclusion (6)

- Primary IgAN, confirmed by kidney biopsy, within 5 years prior to Screening
- eGFR e45 mL/min/1.73 m2, based on the 2021 CKD-EPI equation, at Screening
- Persistent proteinuria, defined as either
- Total Urine Protein e0.5 g/day or UPCR e0.5 g/g in a 24-hour urine collection, at Screening, despite maximally tolerated dose or poorly tolerated supportive therapy or
- IgAN diagnosis \<6 months prior to Screening with Total Urine Protein \>1.5 g/day or UPCR \>1.5 g/g in a 24-hour urine collection, at the time of clinical presentation or diagnosis

... and 1 more (see full listing online)

Exclusion (8)

- Secondary forms of IgAN, as determined by the Investigator, diagnosis of IgA vasculitis, or any other nephropathy or chronic urinary tract disorder
- Total IgG \<6.0 g/L at screening
- Any chronic urinary tract disorder, including but not limited to retention, incontinence, and/or recurrent urinary tract infections
- Untreated hypertension or uncontrolled hypertension despite treatment (i.e., resistant hypertension)
- Treatment with complement pathway inhibitors, mycophenolic acids, systemic calcineurin inhibitors or corticosteroids, immuno-suppressive or immunomodulatory agents within 12 months prior to screening

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

Locations (8 total)

Colorado Kidney Care Nephrology, Denver, Colorado, United States
American Clinical Trials, Acworth, Georgia, United States
Inter Med Consultants, Edina, Minnesota, United States
... and 5 more locations