A Study of Zigakibart in Adults With IgA Nephropathy

Last Update: Apr 10, 2025
A Phase 3, Randomized, Double-blind, Placebo-controlled Study of BION-1301 in Adults With IgA Nephropathy (The BEYOND Study)
ClinicalTrials.gov Identifier:
NCT05852938
Novartis Reference Number:CHK02-02
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

Safety and Efficacy of BION-1301 in Adults with IgA Nephropathy Approximately 272 participants with eGFR ≥ 30 mL/min/1.73m\^2 and with biopsy-proven IgAN will be randomized to receive 600 mg Q2W BION-1301 or a matched placebo for 104 weeks. An additional exploratory cohort, not included in the primary analysis, will be comprised of approximately 20 participants (10 participants per arm) with biopsy-confirmed IgAN and eGFR of ≥ 20 to \< 30 mL/min/1.73 m\^2. The exploratory cohort will be randomized using the same schema as the primary cohort.

The primary objective of the study is to evaluate the effect of BION-1301 versus placebo on proteinuria in adults with IgA nephropathy.

Participants will have assessments of safety and efficacy for 2.5 years (up to 134 weeks). To facilitate study participation over this time period, other visits may be remote (away from study site) for participants who elect to self-administer the study drug.

Condition
IgA Nephropathy, Immunoglobulin A Nephropathy
Phase
Phase3
Overall Status
Recruiting
Number of Participants
292
Start Date
Jul 27, 2023
Completion Date
Jun 07, 2028
Gender
All

Age(s)
18 Years - (Adult, Older Adult)

Interventions

Drug

BION-1301

BION-1301 Pre-Filled Syringe (PFS) 600mg subcutaneous administration every 2 weeks for 104 weeks.
Drug

Placebo

Placebo - PFS subcutaneous administration every 2 weeks for 104 weeks.

Eligibility Criteria

Inclusion Criteria:

* Male and female participants aged ≥ 18 years at the time of signing the informed consent form (ICF) prior to initiation of any study specific activities/procedures.
* Biopsy-proven IgAN diagnosed within the past 10 years prior to Screening, that, in the opinion of the Investigator, is not due to secondary causes. A pseudonymized copy of the report must be available for review by the Sponsor or designee prior to randomization. If biopsy report within 10 years is not available, re-biopsy may be permitted upon discussion with the Sponsor.
* eGFR ≥ 30 mL/min/1.73m\^2 at Screening based on the 2021 CKD-EPI equation.
* Total urine protein ≥ 1.0 g/day or UPCR ≥ 0.7 g/g (700 mg/g), as measured from an adequate 24-hour urine collection at Screening by a central laboratory.
* Stable on a maximally tolerated dose of angiotensin-converting enzyme inhibitors (ACEi) and/or angiotensin II receptor blockers (ARB) for at least 12 weeks prior to Screening unless intolerant to ACEi and ARB. May also be on a stable and well tolerated dose of sodium glucose cotransporter-2 inhibitors (SGLT2i), endothelin receptor antagonists (ERAs) and/or mineralocorticoid receptor antagonists (MRAs) for at least 12 weeks prior to Screening for the treatment of IgAN. Subjects are expected to stay on a stable dose of ACEi, ARB, SGLT2i, ERAs, and/or MRAs for the duration of the study.
* Screening weight of 45 to 150 kg.
* Men and women of childbearing potential (WOCBP; per Clinical Trials Facilitation and Coordination Group \[CTFG\] 2020) must agree to follow protocol-specified contraception guidance from Screening through approximately 5 half-lives (24 weeks) after the final dose of study drug. Use of hormonal contraceptive agents must have been initiated \> 1 month prior to first dose of study drug.
* Provide written informed consent and be willing to comply with study visits and procedures.

Exclusion Criteria:

* Secondary forms of IgAN as determined by the Investigator, in the setting of systemic disorders, infections, autoimmune disorders or neoplasias.
* Diagnosis of IgA Vasculitis.
* Current or history of nephrotic syndrome.
* Average blood pressure \> 150/90 mm Hg (systolic/diastolic) from 3 readings obtained at the initial Screening

visit. If blood pressure is too high, the 3 readings may be repeated once within the Screening period if clinically appropriate as per the Investigator.
* Clinical suspicion of IgAN with rapidly progressive glomerulonephritis (RPGN) based on KDIGO guidelines
* Chronic Kidney Disease, either clinically suspected or based on biopsy, resulting from any condition or another glomerulopathy/podocytopathy other than IgAN.
* History of Type 1 Diabetes.
* Participants with Type 2 diabetes are excluded if any of the following are present:

* Screening HbA1c (glycated hemoglobin) of \> 8%.
* Evidence of diabetic changes on kidney biopsy, performed for any reason.
* History of diabetic microvascular disease (retinopathy, neuropathy, nephropathy) and/or macrovascular disease (atherosclerotic heart disease, peripheral vascular disease, cerebrovascular disease).
* Unstable anti-diabetic regimen:
* Prior exposure to any antibody directed against APRIL.
* History of a previous severe allergic reaction with generalized urticaria, angioedema, or anaphylaxis, including a history of allergy or hypersensitivity to any component of BION-1301, or history of severe hypersensitivity reaction to any monoclonal antibody.
* Received an investigational new drug within 28 days or 5 half-lives, whichever is longer, prior to Screening.
* Received systemic corticosteroid therapy including budesonide (Tarpeyo/Kinpeygo) for \> 14 days within 12 weeks prior to Screening.
* Use of systemic immunosuppressant medications.
* Any confirmed or suspected immunosuppressive or immune-deficient state, including but not limited to common variable immunodeficiency (CVID), HIV infection or asplenia, history of bone marrow or organ transplantation with exception of corneal transplants.
* Current severe infection requiring antimicrobials or history of recurrent, severe, infections as determined by the Investigator.
* Positive serology test for hepatitis A virus IgM antibodies (anti-HAV IgM), hepatitis B surface antigen (HBsAg), detectable hepatitis B virus (HBV) DNA, hepatitis C virus (HCV) antibodies (participants who completed treatment and are persistently antibody be allowed), or antibodies to HIV-1 and/or HIV-2 at Screening.
* Received a live vaccination within 12 weeks prior to Screening or plan to have a live vaccination within 6 months after the last dose of study drug.
* History of malignancy unless cancer free for at least 5 years or non-melanoma skin cancer that was completely resected. A participant with curatively treated cervical carcinoma in situ is eligible for the study. Participants with low-risk prostate cancer (i.e., Gleason score \< 7 and prostate specific antigen \< 10 ng/mL) are allowed.
* Pregnancy or breastfeeding or intent to become pregnant or to donate sperm during the study period and until 24 weeks after last dose.
* History or evidence of any other clinically significant disorder, condition, disease, or laboratory finding that, in the Investigator's assessment, would place the participant at unacceptable risk, limit compliance with study requirements, or confound interpretation of study results.
* IgG levels \< 6 g/L at Screening.
* Participation in another interventional trial with an investigational agent/device is prohibited during the course of this study.

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