A Study to Evaluate the Efficacy and Safety of Sefaxersen (RO7434656) in Participants With Primary Immunoglobulin A (IgA) Nephropathy at High Risk of Progression

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Primary IgAN, as evidenced by a kidney biopsy performed within 10 years prior to or during screening, without known secondary cause * Treatment with maximum tolerated doses of angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs) for at least 90 days immediately prior to screening, and without an intent to modify the dose during the study, except for interruptions due to illness (not greater than 7 consecutive days), unless the potential participant is intolerant to these medications * Urine Protein-to-Creatinine Ratio (UPCR) ≥ 1 gram per gram (g/g) or urine protein excretion ≥ 1 gram per day (g/day) (with UPCR ≥ 0.8 g/g), all measured from a 24-hour urine collection during screening * eGFR ≥ 20 mL/min/1.73 m\^2, as calculated by the 2021 CKD-EPI creatinine equation (Inker et al. 2021a) * Vaccination against Neisseria meningitidis, Streptococcus pneumoniae and Haemophilus influenzae according to national vaccination recommendations * Female participants of childbearing potential must use adequate contraception

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Exclusion Criteria:

* Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 12 weeks after the final dose of sefaxersen * Histopathologic or other evidence of another autoimmune glomerular disease * Presence of ≥ 50% crescents on kidney biopsy, sustained doubling of serum creatinine within 3 months prior to screening, or rapidly progressive glomerulonephritis in the opinion of the investigator * History of kidney transplantation * Glycated Hemoglobin (HbA1c) ≥ 6.5% or a clinical diagnosis of diabetes mellitus of any type * Systolic blood pressure \>140 mmHg or diastolic blood pressure \>90 mmHg from the average of two measurements performed at least 1 minute apart during screening * Initiation of sodium-glucose cotransporter-2 (SGLT2) inhibitors within 16 weeks prior to screening or during screening * Initiation of endothelin receptor antagonists within 90 days prior to screening or during screening * Initiation of mineralocorticoid receptor antagonists or non-dihydropyridine calcium channel blockers within 90 days prior to screening or during screening * Use of herbal therapies within 90 days prior to or during screening * Treatment with investigational therapy within 28 days prior to screening or 5.5 drug-elimination half-lives of that investigational product prior to screening * Treatment with an investigational therapy planned during the treatment period * Previous treatment with sefaxersen * Treatment with oral or intravenous (IV) corticosteroids with a dose equivalent to ≥ 7.5 milligrams per day (mg/day) of prednisone for 7 days or equivalent to ≥ 5 mg/day of prednisone for 14 days within 90 days prior to screening * Treatment with corticosteroids with systemic effects during screening * Treatment with a systemic calcineurin inhibitor within 2 months prior to screening or during screening * Treatment with anti-CD20 therapy within 9 months of screening or during screening * Treatment with other systemic immunosuppressive agents within 6 months of randomization including, but not limited to, complement inhibitors, alkylating agents (e.g., cyclophosphamide or chlorambucil), azathioprine, or mycophenolate * Planned major procedure or major surgery during screening or the study * Substance abuse within 12 months prior to screening or during screening * Any serious medical condition or abnormality in clinical laboratory tests that precludes an individual's safe participation in and completion of the study * History of malignancy within \< 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death * Usage of Glucagon-like Peptide-1 (GLP-1)-based therapy (i.e., GLP-1 mono-agonists, GLP-1/GIP dual agonists, etc.) within 90 days prior to screening or during screening, or intent to initiate during the study period

Conditions & Interventions

Interventions:
DRUG: Sefaxersen (RO7434656), DRUG: Placebo
Conditions:
Primary IgA Nephropathy

More Information

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Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT05797610
