A Phase II, Multi-center, Open-Label Study to Assess Safety, Tolerability, Efficacy and Pharmacokinetics of R3R01 in Alport Syndrome Patients with Uncontrolled Proteinuria on ACE/ARB Inhibition and in Patients with Primary Steroid-Resistant Focal Segmental Glomerulosclerosis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- at least 12 years of age - for people with Alport Syndrome: confirmed diagnosis by genetic testing and /or kidney biopsy - for primary Focal Segmental Glomerulosclerosis (FSGS), (without any identifiable cause, and where the FSGS is confirmed by renal biopsy) or FSGS where there is documentation of a genetic mutation in a podocyte protein - female patients, as well as, female partners of male patients who are of child-bearing potential must be willing to not become pregnant for the complete duration of the study (90 days after the last dose of study medication) - males (including sterilized subjects) whose female partners have child-bearing potential, must agree to use male contraception (condoms) during the period from the time of signing the informed consent form (ICF) through 90 days after the last dose of study drug - contact study staff for additional criteria

Exclusion Criteria:

- uncontrolled diabetes mellitus as evidenced by an HbA1c greater or equal to 11% - uncontrolled high blood pressure - moderate or severe liver impairment - BMI greater than 40 - women who are pregnant or breast feeding - additional exclusion criteria apply (study staff will review)

Conditions & Interventions

Conditions:
Kidney, Prostate & Urinary
Keywords:
Clinics and Surgery Center (CSC), Alport Syndrome, Focal Segmental Glomerulosclerosis

More Information

Description: The main purpose of this study is to check how safe the study drug is and how well your body handles taking it. We will also check if the study drug works to improve your kidney function, if has an impact on your daily life and the amount of the study drug in your blood over a period of time (called pharmacokinetics)
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