A PHASE 2, OPEN-LABEL, SINGLE-ARM, COHORT STUDY TO EVALUATE THE SAFETY, EFFICACY, AND PHARMACOKINETICS OF SPARSENTAN TREATMENT IN PEDIATRIC SUBJECTS WITH SELECTED PROTEINURIC GLOMERULAR DISEASES
(EPPIK)

Status: Recruiting

Eligibility Criteria

Age: Up to 18 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Child 1 to 18 years old 2. Diagnosed by biopsy with specific types of glomerular disease & protein in the urine 3. Blood pressure is within normal range for age 4. Maintained on a stable dose of immunosuppressive medications

Exclusion Criteria:

1. Weight less than 7.3 kg 16 pounds) at screening. 2. Disease due to to viral infections, drug toxicities, or cancer. 3. Kidney function is below the minimum required

Conditions & Interventions

Conditions:

Children's Health, Kidney, Prostate & Urinary, Rare Diseases

Keywords:

Alport Syndrome, Glomerulosclerosis, IgA Vasculitis, Immunoglobulin A Nephropathy

More Information

Description: Currently, there are no approved treatment options for pediatric subjects with proteinuric kidney conditions. The study will look at the safety, efficacy, and pharmacokinetic (PK)trial in children ≥1 to <18 years treated for up to 108 weeks with the drug sparsentan.

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