A Study to Find Out if BI 764198 Helps Adults and Adolescents With a Kidney Condition Called Focal Segmental Glomerulosclerosis (FSGS)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion criteria:

1. Male or female participants ≥12 years old on the day of signing informed consent/assent (Visit 1)
2. Weight of ≥40 kg at the screening visit (Visit 1)
3. Body mass index (BMI) of ≤40 kg/m² at the screening visit (Visit 1)
4. Participants with a diagnosis prior to the screening visit (Visit 1) of either:

- Biopsy-confirmed primary focal segmental glomerulosclerosis (pFSGS) (based on Investigator's judgement) OR
- Genetic focal segmental glomerulosclerosis (FSGS) resulting from a gain-of-function mutation in the transient receptor potential cation subfamily C member 6 (TRPC6) gene (based on historical genetic test)

    1. Urine protein-creatinine ratio (UPCR) ≥1500 mg/g based on the mean of the spot urine sample and first morning void (FMV) urine sample (both assessed by central laboratory) at the screening visit (Visit 1)
    2. Estimated glomerular filtration rate (eGFR)
- For adult participants (≥18 years): ≥25 mL/min/1.73 m² (chronic kidney disease epidemiology collaboration (CKD-EPI) formula based on serum cystatin C) at the screening visit (Visit 1)

- For adolescent participants (12 to <18 years): ≥25 mL/min/1.73 m² based on chronic kidney disease under 25 years (CKiD U25) formula using serum cystatin C at the screening visit (Visit 1) Further inclusion criteria apply.

Exclusion criteria:

1. Known monogenic or syndromic causes of FSGS (with the exception of TRPC6 gain-of-function gene mutations)
2. Clinical or histologic evidence of secondary adaptive or toxic forms of FSGS (based on Investigator's judgement)
3. FSGS of undetermined cause (FSGS-UC) with a diagnosis prior to the screening visit (Visit 1) (based on Investigator's judgement)
4. A history of organ transplantation or planned organ transplantation during the course of the trial
5. Use of intravenous immunosuppressive agents (e.g. cyclophosphamide, rituximab, obinutuzumab) in the last 6 months prior to screening (Visit 1) Further exclusion criteria apply.

Conditions & Interventions

Interventions:
DRUG: BI 764198, DRUG: Placebo
Conditions:
Focal Segmental Glomerulosclerosis

More Information

Description:
PODOMOUNT-pFSGS This study is open to adults and adolescents with a kidney condition called focal segmental glomerulosclerosis (FSGS). The purpose of this study is to find out whether a medicine called BI 764198 helps people with FSGS. Participants are put into 2 groups randomly, which means by chance. Every participant has an equal chance of being in each group. One group takes BI 764198 tablets, and the other group takes placebo tablets. Placebo tablets look like BI 764198 tablets but do not contain any medicine. Participants take a tablet once a day for up to 2 years. All participants also continue their standard medication for FSGS. Participants are in the study for up to 2 years. During this time, they visit the study site about every 3 months. Participants regularly collect urine samples. This is done to check their kidneys. The results are compared between the two groups to see whether the treatment works. The doctors also regularly check participants' health and take note of any unwanted effects.

Contact(s): Ilham Boutahri - Ilham.Boutahri@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE3
IRB Number:
System ID: NCT07220083