

# 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

Age: 12 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

Inclusion criteria: 1. Male or female participants  $\geq 12$  years old on the day of signing informed consent/assent (Visit 1) 2. Weight of  $\geq 40$  kg at the screening visit (Visit 1) 3. Body mass index (BMI) of  $\leq 40$  kg/m<sup>2</sup> 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) 5. Urine protein-creatinine ratio (UPCR)  $\geq 1500$  mg/g based on the mean of the spot urine sample and first morning void urine sample (both assessed by central laboratory) at the screening visit (Visit 1) 6. Estimated glomerular filtration rate (eGFR) \* For adult participants ( $\geq 18$  years):  $\geq 25$  mL/min/1.73 m<sup>2</sup> (chronic kidney disease epidemiology collaboration (CKD-EPI) formula based on combined serum creatinine plus cystatin C) at the screening visit (Visit 1) \* For adolescent participants (12 to  $<18$  years):  $\geq 25$  mL/min/1.73 m<sup>2</sup> based on chronic kidney disease under 25 years (CKiD U25) formula using height and 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 maladaptive 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

**Contact(s):** Boehringer Ingelheim - clintrriage.rdg@boehringer-ingelheim.com

**Principal Investigator:**

**IRB**

**Number:**

**System ID:** NCT07220083

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