A Study of the Efficacy and Safety of DMX-200 in Patients With FSGS Who Are Receiving an ARB

NCT05183646

Status	RECRUITING
Phase	Phase 3
Sponsor	Dimerix Bioscience Pty Ltd
Enrollment	286 participants

Key Eligibility Criteria

Inclusion (19)

- DOUBLE BLIND PERIOD
- Patients must be 12 to 80 years old
- A diagnosis of primary FSGS, genetic FSGS, or FSGS of undetermined cause. Confirmed by kidney biopsy within 7 years of screening
- Must be either receiving an ARB at the maximal tolerated dose or willing to transition
- If taking corticosteroids, the dosage must be stable for e4 weeks prior to Screening and during Stabilization

... and 14 more (see full listing online)

Exclusion (21)

- Has FSGS secondary to another condition.
- Patients with nephrotic syndrome (\>3.5 g/day proteinuria and serum albumin \<30 g/L) who have not previously been treated with standard of care FSGS-directed therapies (including steroids).
- History of type 1 diabetes mellitus, or uncontrolled type 2 diabetes mellitus (defined as glycated hemoglobin \[HbA1c\] \>8% at Screening)
- History of lymphoma, leukemia, or any active malignancy within the past 2 years (except for basal cell or squamous cell carcinomas of the skin or cervical carcinoma in situ that have been resected and with no evidence of metastatic disease).
- Active clinically significant hepatobiliary disease.

... and 16 more (see full listing online)

Locations (220 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
Phoenix Children's Hospital, Phoenix, Arizona, United States
Arizona Kidney Disease and Hypertension Center, Phoenix, Arizona, United States
... and 217 more locations