Now Enrolling: The EPPIK Clinical Study for Children with Rare Glomerular Diseases

Travere is now enrolling a Phase 2, open-label, single-arm, cohort study to evaluate the safety, efficacy, and pharmacokinetics of sparsentan in pediatric patients (ages 1 to 17) with selected proteinuric glomerular diseases.

What is sparsentan?

Sparsentan is a novel Dual Endothelin Angiotensin Receptor Antagonist (DEARA). It is a dual acting, highly selective antagonist of both the endothelin A receptor (ET_AR) and the angiotensin II subtype 1 receptor (AT_1R).

EPPIK Study Details

The EPPIK Study is evaluating 2 patient populations:

Population 1:
Patients with FSGS or MCD

Population 2:
Patients with IgA nephropathy, IgA vasculitis, or Alport syndrome

All patients receive a once daily oral administration with sparsentan as a liquid at a dose determined by the study population and calculated based on age and weight. The study, including screening and treatment period, lasts 116 weeks and includes up to 18 study visits. The primary endpoints are the incidence of adverse events as well as change in UP/C from baseline over the 108-week treatment period. Approximately 60 children will participate in study sites in Europe and the United States.

Key Eligibility Criteria – Overall

- Patient has eGFR≥30 mL/min/1.73 m^2 at screening
- Patient weighs ≥7.3 kg
- No kidney transplantation or dialysis
- No FSGS or MCD histological pattern secondary to viral infections, drug toxicities, or malignancies
- No IgA glomerular deposits secondary to another condition
- No acute onset, presentation or relapse of glomerular disease requiring new or different class of IST treatment within 6 months before screening

Please see population-specific eligibility criteria on the following page

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Key Eligibility Criteria for Population 1

- Male or female, ≥1 year at screening to <18 years of age
- UP/C ≥1.5 g/g at screening **AND** one of the following:
  - Biopsy-proven FSGS or MCD histological patterns with consistent clinical presentation, with history or ongoing treatment with corticosteroids and/or other immunosuppressive agents
  - Documentation of a genetic mutation in a podocyte protein associated with FSGS or MCD
  - Biopsy-proven FSGS histological pattern with medical history and clinical presentation consistent with maladaptive cause

Key Eligibility Criteria for Population 2

- Male or female, ≥2 years to <18 years of age
- Patient has UP/C ≥1.0 g/g at screening **AND** one of the following:
  - Biopsy-confirmed IgA nephropathy or IgA vasculitis
  - Alport syndrome (documentation of pathogenic COL4A3/4/5 mutation[s])

Screening (≤8 weeks)

- Standard of care
- Confirm eligibility
- Informed consent
- Week -2: 2-week washout period (no RAAS inhibitors)

Study Cohorts

Population 1 (FSGS and/or MCD)

- Cohort 1
- Cohort 2
- Cohort 3

Population 2 (IgAN, IgAV or AS)

- Cohort 1
- Cohort 2
- Cohort 3

Week 1 to Week 108

Dosing:

- Once-daily dosing of sparsentan

Assessments:

- Safety, tolerability and clinical response
- PK (Day 1, Day 2 and Week 12)

FSGS = focal segmental glomerulosclerosis; MCD = minimal change disease; IgAN = immunoglobulin A nephropathy; IgAV = immunoglobulin A vasculitis; AS = Alport syndrome; RAAS = renin-angiotensin-aldosterone system; PK = pharmacokinetic

For more information, please visit clinicaltrials.gov **NCT05003986**, clinicaltrialsregister.eu, EudraCT: **2021-000621-27**, kidneyhealthgateway.com or contact medinfo@travere.com.

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