Post Approval Study for Treatment of Drug-resistant Adult and Pediatric Primary FSGS Using the LIPOSORBER® LA-15 System

Status: RECRUITING

Eligibility Criteria

Age: Up to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

A patient is deemed suitable for inclusion in the study if the patient has nephrotic syndrome associated with primary FSGS when: • Standard treatment options, including corticosteroid and/or calcineurin inhibitors, are unsuccessful or not well tolerated and the patient's glomerular filtration rate (GFR) ≥ 45 ml/min/1.73 m2. or • The patient is post renal transplantation.

Exclusion Criteria:

General Exclusion Criteria 1. Patient is greater than 75 years of age at the start of the treatment period or less than 22 2. The patient is unwilling or unable to sign and date the informed consent 3. Pregnant, lactating, or planning to become pregnant prior to completing the study (Note: The safety of the use of LIPOSORBER® in pregnant women has not been studied. There may be unknown risks to an embryo/fetus. Sexually active women of childbearing potential should avoid pregnancy during the use of the LIPOSORBER device and throughout the study duration.) 4. Unable or unwilling to comply with the follow-up schedule 5. Simultaneously participating in another investigational drug or device study 6. Body weight \< 15 kg (33.1 lbs) Medical Exclusion Criteria 1. Currently being administered ACE inhibitors that cannot be withheld for at least 24 hours prior to each apheresis treatment (Note: The time period to withhold ACE inhibitors should be prolonged, if determined by the treating physician, considering each individual's renal function and the biological half-life of the ACE-inhibitor currently in use.) 2. Currently being administered antihypertensive drugs other than ACE inhibitors (e.g., ARBs) that cannot be withheld on the day of apheresis until after the procedure 3. Medical condition or disorder that would limit life expectancy to less than the primary clinical study endpoint or that may cause noncompliance with the study plan or confound the data analysis 4. Hypersensitivity to dextran sulfate, heparin, or ethylene oxide 5. Adequate anticoagulation cannot be achieved due to severe hemophilia, severe hemorrhage diathesis, severe gastrointestinal ulcers, or are recipients of vitamin K antagonist medications 6. Extracorporeal circulation therapy with LIPOSORBER® LA-15 System cannot be tolerated due to severe cardiac insufficiency, acute myocardial infarction, severe cardiac arrhythmia, acute apoplexy, severe uncontrollable hypertension, or severe uncontrollable hypotension Note: Severe uncontrollable hypotension/hypertension indicates the cases with systolic and/or diastolic blood pressure ≤ 5th percentile for age, gender, and height. 7. Cardiac impairments such as uncontrolled arrhythmia, unstable angina, decompensated congestive heart failure, or valvular disease 8. Functional thyroid disease or liver abnormalities 9. Unresolved systemic or local infection that could affect the clinical study outcomes

Conditions & Interventions

Interventions:
DEVICE: LIPOSORBER® LA-15
Conditions:
Focal Segmental Glomerulosclerosis
Keywords:
FSGS, Liposorber

More Information

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