**Liposorber® LA-15 system for LDL apheresis in drug resistant primary focal segmental glomerulosclerosis patients: Interim results from a prospective, multicenter, single-arm intervention study**

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**Background:** Focal segmental glomerulosclerosis (FSGS) is the major cause of end stage renal disease (ESRD) in the United States and worldwide. Primary FSGS carries poor prognosis as spontaneous remission is rare and more rapidly progress to ESRD within 2-8 years in nephrotic range proteinuria patients. Management of FSGS patients refractory to standard treatments or resistant to steroids remains a major challenge. Low-density lipoprotein apheresis (LDL apheresis) is a novel therapy for drug resistant (corticosteroids and/or calcineurin inhibitors) primary FSGS and post-renal transplant primary FSGS recurrence.

**Objectives**: To examine the safety and probable benefit at 1, 3, 6, 12 and 24 months following completion of apheresis treatment using Liposorber® LA-15 system in patients with NS due to refractory primary FSGS, or primary FSGS associated NS in post renal transplant children.

**Material and methods:** Prospective, multicenter, single-arm intervention study using Liposorber® LA-15 system. Study was initiated in July 2014 with expected enrollment completion in August 2018. Patients ≤21 years old with drug resistant or drug intolerant NS secondary to primary FSGS with glomerular filtration rate (GFR) ≥60 ml/min/1.73m2 or post renal transplant patients ≤21 years old with primary FSGS associated NS were included in the study. Each patient will have a total of 12 apheresis sessions with Liposorber® LA-15 system over a period of 9 weeks. All the patients will be followed up at 1, 3, 6, 12 and 24 months following completion of apheresis treatment.

**Interim results:** As of October 2017, 14 patients from 6 sites have been enrolled in to the study. A total of 11 patients completed 12 apheresis treatments over a period of 9 weeks. Three of seven patients (43%) attained partial remission of NS at 1-month follow-up visit. Furthermore, 4 of 6 subjects (66.6%) and 3 of 4 subjects (75%) had partial/complete remission at 3 and 6 months following LDL apheresis respectively. Of 3 patients who were followed up for 12 months, 2 had complete remission and one had persistence of NS. Improvement or stable eGFR was noted in majority of patients (70%) over the follow-up period.

**Conclusion:** In line with other previous studies, short-term results of our multicenter study showed improvement in the response rates to steroid or immunosuppressive therapy and induce complete or partial remission of proteinuria in drug resistant primary FSGS patients. However, these are interim results and full analysis after completion of the study will through more light on the outcome of LDL apheresis using Liposorber® LA-15 system.