

**Title:**

*A phase 2 study to evaluate the efficacy and safety of Lorundrostat alone, and Lorundostat in combination with Dapagliflozin, in adults with Hypertension and Chronic Kidney Disease with Albuminuria*

**Overview**

This is a study evaluating the efficacy and safety of lorundrostat (an ASI) in the treatment of hypertension in subjects with CKD and albuminuria despite receiving stable treatment with an ACEi or an ARB either in combination with dapagliflozin, an SGLT2i, or alone.

**Indication:**

Hypertension and Chronic Kidney Disease (CKD) with Albuminuria.

**Objectives & Endpoints**

To assess the effect of lorundrostat 25 mg once daily (QD), in addition to a sodium-glucose cotransporter-2 inhibitor (SGLT2i), on systolic blood pressure (SBP) in subjects with hypertension and chronic kidney disease (CKD) with albuminuria on stable treatment with an angiotensin converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB)

**Study Compensation:**

\$50 per visit up to a total of \$500.

**Study Duration:**

The expected duration of the study for each subject from Screening to the end of study visit is expected to be:

- Approximately 18 weeks

**Investigational Product:**

Clinical data obtained from healthy volunteers as well as patients with uncontrolled hypertension and RH have shown that Lorundrostat has been well tolerated and has an acceptable safety profile.

**Major Eligibility Criteria:****Major Inclusion Criteria:**

- UACR of 200-5000 mg/g, inclusive, at Screening
- eGFRs  $\geq 30$  mL/min/1.73 m<sup>2</sup>
- SBP of 133-180 mmHg, inclusive
- On a stable treatment with an ACEi or ARB for at least 4 weeks
- BMI of  $\geq 18$  kg/m<sup>2</sup>,

**Major Exclusion Criteria:**

- Previous treatment with lorundrostat within 4 weeks
- Known allergy to lorundrostat or dapagliflozin,
- Serum potassium  $>5.0$  mmol/L
- Clinically significant hyponatremia within 1 year of screening
- Arm circumference  $>55$  centimeters
- Kidney disease related to autoimmune diseases, renal transplant
- History of heart failure, myocardial infarction, stroke, or transient ischemic attack within 6 months