A Prospective, Observational, Multicenter Evaluation of A Novel Formulation of Furosemide (SCP-111) Administered Subcutaneously

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STUDY DRUG

SCP-111 (furosemide injection), 80 mg/mL is an investigational proprietary isotonic, furosemide formulation buffered to a neutral pH and administered as a single dose via subcutaneous (SC) injection.

OBJECTIVES

- Describe the population of patients with heart failure (HF) and/or chronic kidney disease (CKD) who receive SCP-111 for treatment of fluid overload (FO) or who are at risk for FO
- Evaluate treatment patterns of SCP-111 for FO in patients with HF and/or CKD
- Describe signs and symptoms of FO in patients with HF and/or CKD treated with SCP-111
- Evaluate safety of SCP-111 in patients with HF and/or CKD

ENDPOINTS

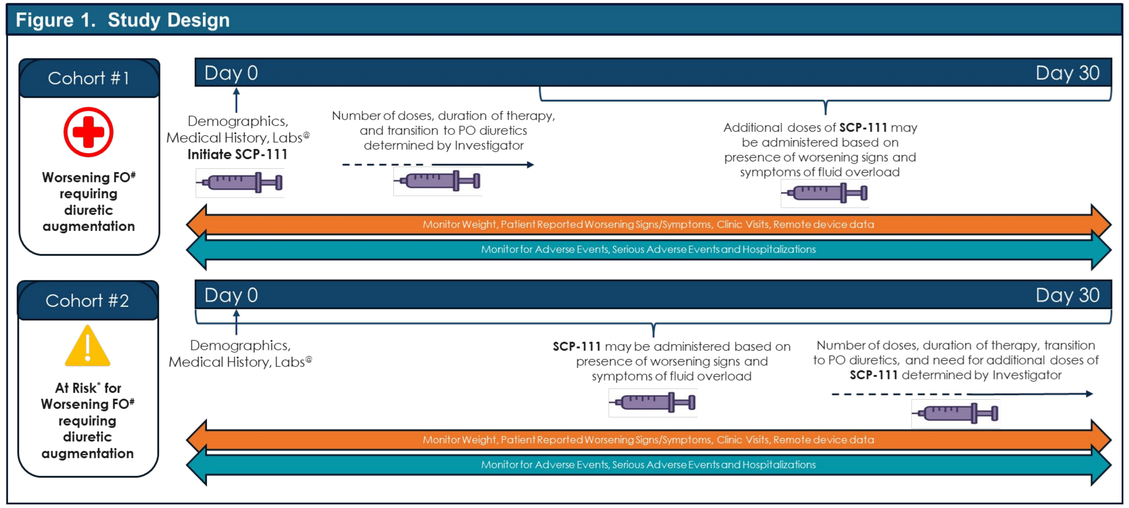
- Signs/symptoms of FO triggering use of SCP-111
- Days from study entry to 1st dose of SCP-111
- Concomitant diuretic use and dosing with SCP-111
- Number and frequency of doses of SCP-111 per FO episode
- Change in body weight 24 hours after each SCP-111 dose
- Change in signs and symptoms 24 hours after each SCP-111 dose
- Change in 5-point Dyspnea Score 24 hours after each SCP-111 dose
- 30-day home time:
  - Days alive and outside of hospital and/or skilled-nursing facility for study period
- Adverse Events (AEs) and Serious Adverse Events (SAEs) through study period

DESIGN AND METHODOLOGY

- Prospective, observational, multicenter study of two patient populations:
  - **Cohort 1:** Patients with worsening signs/symptoms of FO requiring augmented diuretics
  - **Cohort 2:** Patients at risk for hospitalization from worsening signs/symptoms of FO within 30-days
- Patients who satisfy inclusion/exclusion criteria will be followed for 30 ± 5 days
- Once enrolled, all episodes of worsening FO will be treated with SCP-111
  - May be enrolled upon hospital discharge or during clinic visit

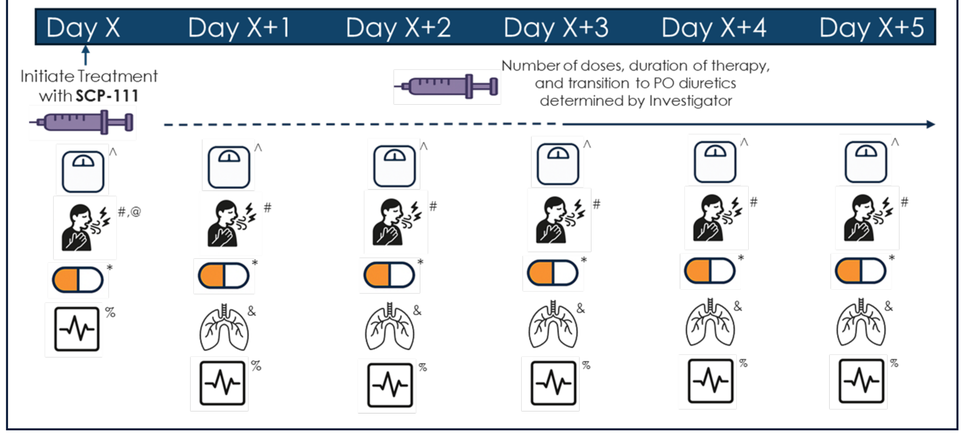
DESIGN AND METHODOLOGY, cont.

Figure 1. Study Design



Jugular venous distention, edema, ascites, S3 heart sound, pulmonary rales, hepatomegaly, pulmonary congestion on chest X-ray, dyspnea, orthopnea, fatigue, exercise intolerance
* Hospitalization with fluid overload (received IV Diuretics) due to HF or CKD in prior 3 months OR Episode of worsening signs and symptoms of fluid overload in past 30 days
@ Baseline Labs: Na, K, Cl, CO_2, BUN, SCr, Glucose, Mg, NT-proBNP, LFTs, Albumin, Total Protein, Urinalysis

Figure 2. Assessments Upon SCP-111 Administration



Signs/symptoms of FO: Jugular venous distention, edema, ascites, S3 heart sound, pulmonary rales, hepatomegaly, pulmonary congestion on chest X-ray, dyspnea, orthopnea, fatigue, exercise intolerance
@ Denote which signs and symptoms were triggers for initiation of SCP-111
^ Weight; * Concomitant Diuretics; % Remote monitoring data, if available; & 5-Point Dyspnea Score

ELIGIBILITY CRITERIA

- **Inclusion Criteria:** *All criteria must be met*
  - ≥ 18 years of age
  - Diagnosis of HF and/or CKD, including nephrotic syndrome
  - Does not require immediate hospitalization
  - Ability to participate in study per Investigator
  - Either of the following clinical scenarios:
    - **Cohort 1 (Symptomatic):** On chronic loop diuretics with worsening signs/symptoms of FO requiring augmentation of diuretics
    - **Cohort 2 (At-Risk):** On chronic loop diuretics at risk for hospitalization due to worsening signs/symptoms of FO over next 30 days as defined by:
      1. Been hospitalized or had an Emergency Room (ER) visit with fluid overload in past 30 days AND received IV diuretics, OR
      2. Had episode of worsening signs/symptoms of FO in past 30 days requiring diuretic augmentation
- **Exclusion Criteria:** *Any criteria will exclude*
  - Pregnant or lactating, or women of childbearing age not willing to use adequate contraception
  - Suspected high risk clinical instability with outpatient treatment
  - Presence of complicating condition (other than HF or CKD) likely to require hospitalization within 30 days
  - Anuria
  - On experimental medication or participation on another interventional research study
  - History of severe allergic/hypersensitivity reactions to furosemide or inactive ingredients of SCP-111

RECRUITMENT INFORMATION

- **Number of participants:** Approximately 150
- **Number of sites:** Approximately 10
- **Participating Countries:** United States
- **Estimated Start Date:** 2H 2026

More Details/Participation Interest:

US-FUR-25-00170