

scPharmaceuticals Announces Start of SUBQ-HF NHLBI Study with Its Subcutaneous Furosemide Product

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LEXINGTON, Mass., January 24, 2017 /PRNewswire/ – scPharmaceuticals, Inc., a privately held biopharmaceutical company developing transformative pharmaceutical products for subcutaneous delivery, announced today the start of the first phase of a study conducted by the Heart Failure Clinical Research Network (HFN). HFN is a clinical research initiative funded by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). The primary goal of the HFN is to conduct multiple clinical trials to evaluate treatments and strategies to improve management of acute and chronic heart failure.

SUBQ-HF is the abbreviated name for "Subcutaneous Furosemide in Acute Decompensated Heart Failure." The purpose of SUBQ-HF is to evaluate a strategy of early hospital discharge to home with daily subcutaneous furosemide administration by patient or lay caregiver. In this study the new strategy will be compared to usual care, which typically involves a hospital stay of three to seven days and treatment with intravenous diuretics.

The SUBQ-HF trial program includes a two-part, non-comparative pilot phase followed by a randomized comparative trial which compares usual inpatient care with a strategy of a short in-patient stay followed by two to seven days of at-home treatment with the sc2Wear Furosemide Infusor. Enrollment for the pilot phase started in January of 2017. The anticipated read out of the SUBQ-HF study program is in 2018. Five centers are participating in the pilot phase including Emory University Hospital, Massachusetts General Hospital, Mayo Clinic, Duke University Medical Center and Metro Health System. The main study is expected to include up to an additional 20 centers in the US. The Protocol Principal Investigator of the study is Michael Felker, MD, Duke University. Eugene Braunwald, MD, Harvard University, acts as the Study Chair.

"One of the core objectives of healthcare reform is to concurrently improve treatment outcomes while reducing cost of care." said Pieter Muntendam, MD, president and CEO of scPharmaceuticals. "Patients with heart failure make up 42 percent of all Medicare admissions and in 2012 we set out to develop a product that would offer a home-based, hospital-strength diuretic option for treatment of fluid overload in heart failure, the single most common reason for these hospitalizations. The NHLBI SUBQ-HF will help to define how to best use this novel option to reduce length of stay."

About scPharmaceuticals:

scPharmaceuticals, based in Lexington, MA, is a privately held biopharmaceutical company developing a portfolio of transformative pharmaceutical products for subcutaneous delivery. Based on widely used generic drugs that currently require intravenous or intramuscular injections, innovative products will be administered subcutaneously via a proprietary patch pump. This avoids material risks and costs associated with the current delivery options. Our lead products are the first subcutaneous formulation of furosemide (the most widely used parenteral diuretic in treating heart failure), and ceftriaxone (the most widely used parenteral antibiotic used outside the hospital setting). Our novel furosemide formulation enables convenient anytime anywhere use, for example in an outpatient setting instead of the emergency room or other in-patient settings. For ceftriaxone and other antibiotics, subcutaneous administration eliminates the need for PICCs (peripherally inserted central catheters), which are associated with serious complications, frequent adverse events and high medical cost.

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