scPharmaceuticals Announces Presentations on Subcutaneous Furosemide at HFSA Annual Meeting

-Complete bioavailability and equivalent diuresis after subcutaneous administration under experimental conditions

- Equivalent diuresis when compared to high dose IV in heart failure patients in need of treatment of fluid overload

LEXINGTON, Mass., September 19, 2016 /PRNewswire/ -- scPharmaceuticals, Inc., a privately held biopharmaceutical company developing transformative pharmaceutical products for subcutaneous delivery, announced today the presentation of results of two studies at the 20th Annual Heart Failure Society of America (HFSA) Scientific Meeting in Orlando, Florida.

Dr. Domenic Sica, Professor of Medicine and Pharmacology at the Medical College of Virginia Commonwealth University in Richmond and immediate past president of the American Society of Hypertension, presented the study titled "Pharmacokinetic and Pharmacodynamic Response after Subcutaneous Administration of a Novel Furosemide Formulation." The cross-over study in patients with heart failure compared subcutaneous administration of a novel furosemide formulation with intravenous (IV) administration of furosemide USP (the commercial reference product). The study was conducted in 16 patients and the results indicated that therapeutic plasma levels were achieved within 30 minutes in all subjects and that complete bioavailability was achieved following subcutaneous administration (99.65% for AUCinf). Diuresis after subcutaneous administration of the novel formulation using a proprietary biphasic delivery profile was also fully equivalent to IV administration of furosemide USP in accordance with the FDA approved prescribing information (102% and 103% for 0–8h and 0–24h).

"Fluid overload in heart failure interferes with oral absorption of the drugs used to treat it" said Dr. Sica. "This study indicates that subcutaneous administration of a novel formulation over five hours achieves complete bioavailability and equivalent diuresis when compared to intravenous administration in accordance with prescribing information for standard furosemide. This would provide an important novel alternative for the many heart failure patients who periodically require more diuresis than oral medication alone can provide, and enable a new care model that minimizes inpatient care."

Dr. Stuart Russell, Chief, Heart Failure and Transplantation and Associate Professor of Medicine at Johns Hopkins University Medical School, presented the results of an ongoing study titled "Efficacy and Safety of Subcutaneous versus Intravenous Furosemide in an Ambulatory Heart Failure Population." The randomized, comparative study involving 26 patients compared usual care at the Johns Hopkins

diuresis outpatient infusion clinic consisting of high dose IV furosemide given by bolus injection, with 80mg of the novel furosemide formulation administered subcutaneously over five hours using a proprietary biphasic delivery profile. The results indicated that the subcutaneous treatment of 80mg over five hours resulted in equivalent diuresis when compared to an average of 128 mg given by IV bolus injection.

“Fluid overload is the primary driver of healthcare utilization by patients with heart failure” said Dr. Russell. “Intravenous administration of furosemide has been the cornerstone treatment for nearly 50 years. Our data supports that subcutaneous administration of the novel formulation may provide a much needed alternative to offer the first hospital-strength diuretic treatment option that patients and lay caregivers could use at home, as directed by their prescriber.”

"The Affordable Care Act of 2010 aligned incentives for hospitals and physicians to reduce the reliance on inpatient care for the treatment of patients with heart failure, which make-up a staggering 42 percent of all admissions paid for by Medicare Fee for Service,” said Pieter Muntendam, MD, President and CEO of scPharmaceuticals. “We set out to create a product that could transform care for heart failure patients with fluid overload by offering an alternative to costly and burdensome in-hospital care. The data presented here at the Annual HFSA Scientific Meeting suggests that we have achieved this objective and that we can now start a process with patients, providers and payors to determine how to best use this new option to materially reduce the burden of heart failure for individuals and society at large.”

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. For further information on how we are transforming the administration of parenteral drugs, go to www.scpharmaceuticals.com.

For More Information:

Katherine Taudvin
Director Corporate Development
Email: ktaudvin@scpharma.com
Telephone: (781) 301-6706