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## **scPharmaceuticals Announces Start of Pivotal Trial for Novel Furosemide Solution for Subcutaneous Delivery**

Novel formulation and proprietary patch pump would offer a new and different option for the management of fluid overload in heart failure.

LEXINGTON, Mass., April 21, 2015 /PRNewswire/ -- scPharmaceuticals, Inc., a privately held biopharmaceutical company developing transformative pharmaceutical products for subcutaneous delivery, announced today that it has commenced its pivotal trial of its investigational proprietary drug product, Furosemide Injection Solution, for the treatment of edema associated with congestive heart failure.

Concurrently with its pharmaceutical development, scPharmaceuticals is developing a proprietary patch pump. The patch pump is designed to enable convenient and comfortable subcutaneous administration of injectable pharmaceuticals without the resources and costs associated with intravenous or intramuscular administration. scPharmaceuticals anticipates submitting a 505(b)(2) NDA in the fourth quarter of 2015 for the drug-device combination.

Furosemide Injection Solution is scPharmaceuticals' first pipeline product entering the final stage of development. The product is intended to reduce the dependence on emergency room and inpatient treatment of heart failure, which is estimated to cost approximately \$10b in the US alone.

The company's novel and proprietary formulation of furosemide was optimized for subcutaneous administration by reducing the pH to a neutral and physiologic level to minimize risk of local irritation or discomfort. Without the proprietary buffering method, furosemide is practically insoluble and unstable at physiologic pH. The novel formulation was the result of the company's pharmaceutical research and is the subject of a 2013 patent application. Furosemide was developed in the 1960s and was commercialized under the brand name Lasix®. Furosemide is one of the most widely used prescription pharmaceuticals in the US in both oral and intravenous forms. Furosemide has not previously been developed or approved for subcutaneous administration.

The novel Furosemide Injection Solution for subcutaneous administration via a patch pump provides an alternative to intravenous furosemide. It has applications in a broad range of settings including use in outpatient clinics, nursing homes, hospice centers and home health. It is intended to facilitate more effective outpatient diuresis and hence avoid emergency room care and hospital admissions.

The study is conducted in the US under the company's investigational new drug (IND) application. The pivotal clinical study is part of a development program for which the company sought and received input from the FDA through in-person meetings and correspondence.

"The sole reason for emergency room or in-patient care for most heart failure patients is removal of excess fluid with the average admitted patient losing over two gallons in a little over five days at a cost of over \$8,000 per gallon," said Pieter Muntendam, President, CEO and founder of scPharmaceuticals. "This product concept was brought to us by leaders in the heart failure community as a new tool to

prevent readmissions and materially reduce the overall burden of heart failure to patients, payors and clinicians.”

**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, our 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 formulations of furosemide (the most widely used parenteral diuretic in treating heart failure) and ceftriaxone (the most widely used parenteral antibiotic 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](http://www.scpharmaceuticals.com).

**For More Information:**

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