Strategic Science & Technologies

Strategic Science & Technologies, LLC (SST) Initiates Phase 2 Study to Evaluate Topical Sildenafil in Men with Erectile Dysfunction

SST-6006 is a first-in-class topical sildenafil product candidate in development as an over-the-counter treatment for erectile dysfunction

CAMBRIDGE, Mass. – June 17, 2015 - Strategic Science & Technologies, LLC (SST), a clinical stage biotechnology company developing novel first-in-class topical formulations of known pharmaceutical products, announced the initiation of a Phase 2 trial of SST-6006 in men with erectile dysfunction. SST-6006 is a first-in-class topical sildenafil product candidate in development for the treatment of erectile dysfunction (ED) in men. The oral formulation of sildenafil is marketed by Pfizer as Viagra®.

"Having successfully demonstrated the safety and tolerability of SST-6006 in healthy men and women, the initiation of this Phase 2 clinical trial in men with ED is an important step forward in our plan to pursue the potential registration of SST-6006 as a first-in-class over-the-counter topical product to meet the significant sexual health needs in both men and women," said Eric T. Fossel, Scientific Founder of SST.

The Phase 2, double-blind, placebo-controlled trial will evaluate the safety and efficacy of SST-6006 in men with ED following a single 2ml dose (formulated to deliver 100mg of sildenafil citrate) applied topically to the entire penis. The study will evaluate 30 patients and utilize penile plethysmography (RigiScan®) to measure the effectiveness of SST-6006 on both penile rigidity and erection duration. The two-center study is being conducted by Dr. Irwin Goldstein, Director of San Diego Sexual Medicine and Clinical Professor of Surgery at the University of California at San Diego, and Dr. Wayne Hellstrom, Professor of Urology and Chief of Andrology at Tulane University School of Medicine. More information about the Phase 2 study with SST-6006 can be found on ClinicalTrials.gov under the trial identifier, NCT02390960.

This Phase 2 trial follows a recently completed Phase 1 trial in which SST-6006 was found to be well tolerated in healthy men, with a significantly reduced number of side effects compared to oral sildenafil. All side effects were mild and transient in nature. The peak concentration of sildenafil detected in the blood after a single application of SST-6006 was shown to be significantly less than that detected from a comparable strength oral dose of sildenafil. These results suggest that a single topical application of SST-6006 could deliver a clinically meaningful concentration of sildenafil to the local target tissue (penis), but without the systemic side effects more commonly associated with the use of oral sildenafil.

About Erectile Dysfunction

Erectile dysfunction (ED), a sexual dysfunction affecting an estimated 13-20% of men aged 40 to 80, is characterized by the inability to develop or maintain an erection during sexual activity. Phosphodiesterase type-5 (PDE-5) inhibitors are considered the standard-of-care in first-line ED treatment. Oral PDE-5 inhibitors such as sildenafil have been administered as treatments for ED for over 15 years and have made a significant impact in the sexual well-being of patients. However, because oral PDE-5 inhibitors are currently only available with a prescription and have well documented side effects, the vast majority of patients with ED do not receive oral PDE-5 inhibitors. Studies have reported that of the projected 18 million men with ED, only 16% are treated with oral PDE-5 inhibitor therapy.

About SST-6006

SST-6006, developed with SST's proprietary KNOSIS™ technology, is a patented topical cream product containing 5% sildenafil citrate by weight. The marketed oral formulation of sildenafil, Viagra®, is a specific PDE-5 inhibitor that enhances nitric-oxide mediated vasodilation of blood vessels in the corpus cavernosum of the penis, and is evidenced to act analogously in the smooth muscle cells of the female clitoris, vagina and labia minora. When sexual stimulation causes local release of nitric oxide, inhibition of PDE-5 by sildenafil results in smooth muscle relaxation and inflow of blood to the target tissue. Viagra® is available as a prescription drug for men; however, it is not approved for use in women. Its use is contraindicated in some men due to its systemic vasodilatory properties that result in decreased supine blood pressure. In patients without these cardiovascular risk factors, mild and temporary side effects include headache, facial flushing, upset stomach and nausea. The FDA-approved labeling for PDE-5 inhibitors also includes warnings about the risk for sudden loss of vision in one or both eyes and sudden decrease or loss of hearing.

SST is concurrently developing an identical topical sildenafil preparation (i.e. SST-6007) for women with female sexual arousal disorder (FSAD), which has recently completed Phase 1 clinical testing.

About KNOSIS™

SST's novel topical technology, KNOSIS™, is based on the pioneering work of its Scientific Founder Eric T. Fossel, formerly in the Biochemistry, Biophysics and Radiology Departments at Harvard Medical School. Due to the skin's highly protective barrier, the stratum corneum, success with topical delivery approaches has been mostly limited to smaller, uncharged molecules. SST's proprietary topical delivery technology overcomes these historical challenges through at least two novel features. First, the KNOSIS formulation technology produces a hostile biophysical environment for the active pharmaceutical ingredient (API), increasing its free energy and creating a positive chemical potential which drives the API from the delivery vehicle into the tissue. Second, this novel formulation prevents the formation of hydrogen bonds between the API and the stratum corneum, which can inhibit the ability of the API to permeate into the tissue. These two complementary actions support SST's efforts to achieve the desired local therapeutic effect in the target tissue and, due to the minimal uptake of the drug into the bloodstream, greatly reduce or eliminate any known side effects associated with its systemic absorption.

About Strategic Science & Technologies, LLC

Strategic Science and Technologies LLC (SST) is a clinical-stage biotechnology company developing first-in-class topical formulations of known pharmaceutical products. SST has been successful in delivering several highly-charged molecules across the skin in therapeutic areas including pain, dermatology, and men's and women's sexual health. By working only with FDA-approved drugs, SST utilizes the 505(b)(2) regulatory pathway to accelerate the development of topical formulations and is advancing a portfolio of both OTC and prescription drug product candidates. SST remains privately funded by its original private investors, with a business strategy to partner its products with experienced pharmaceutical companies prior to initiation of the pivotal Phase 3 registration trials. www.strategicscience.com

Media Contact:
Hunter Marshall or Kari Watson
MacDougall Biomedical Communications
(650) 342-1000 or (781) 235-3060
hmarshall@macbiocom.com or kwatson@macbiocom.com