Strategic Science & Technologies

Strategic Science & Technologies (SST) Initiates Phase 2 Study to Evaluate Topical Sildenafil in Women with Female Sexual Arousal Disorder

SST-6007 is a first-in-class topical sildenafil product candidate in development as an over-the-counter treatment for Female Sexual Arousal Disorder

CAMBRIDGE, Mass. – October 28, 2015 - Strategic Science & Technologies, LLC (SST), a clinical stage biotechnology company developing novel topical formulations of known pharmaceutical products, announced the initiation of a Phase 2 clinical proof-of-concept trial of SST-6007, a first-in-class topical product candidate in development for the treatment of Female Sexual Arousal Disorder (FSAD). SST-6007 contains sildenafil citrate, the active drug component in Viagra®, which is currently marketed by Pfizer for the treatment of erectile dysfunction in men.

"The need for FSAD treatments has never been clearer than it is now, with the demands for new therapies to treat sexual dysfunction in women gaining widespread public support. We believe the development of SST-6007 is a very important step in addressing this critical unmet need. Following encouraging results from our Phase 1 study, we are pleased to continue to advance this important treatment that could positively impact the lives of the many women who suffer from FSAD," said Eric T. Fossel, Scientific Founder and Chief Executive Officer of SST.

The Phase 2, double-blind, placebo-controlled, two-way crossover clinical trial will evaluate the efficacy and safety of SST-6007 in women with FSAD following a single 2 gram dose (100 mg sildenafil citrate) applied to the local vulvar-vaginal target site. The study will enroll 30 women with FSAD, 15 pre-menopausal and 15 post-menopausal, and will assess physiological genital response (as measured using a vaginal photoplethysmograph) and subjective sexual arousal (as measured by a Likert-scale questionnaire and Arousometer device). Secondary objectives will include time to onset of action and safety. The single-center study is being conducted at the Sexual Psychophysiology Laboratory at the University of Texas Austin. More information about the Phase 2 study with SST-6007 can be found on ClinicalTrials.gov under the Identifier number NCT02570282.

Principal Investigator for the study, Cindy M. Meston, Ph.D., Professor, The University of Texas at Austin, Director, The Sexual Psychophysiology Laboratory commented, "There are several different types of sexual problems women experience. The drug that was recently approved by the FDA aims to help women with desire problems. The drug being tested in my lab, SST-6007, is designed to help women who have problems becoming sexually aroused. Many women report wanting to engage in sex but find that their bodies do not respond sexually like they once did, and this often dramatically decreases their overall sexual pleasure. If SST-6007 works as we expect it will, it could have far-reaching consequences for women with sexual arousal dysfunction."

In a recently completed Phase 1 trial in healthy post-menopausal women, SST-6007 was found to be safe and well tolerated with no dermal irritation reported following a clinically relevant dose. Systemic side effects were mild and transient in nature with no clinically meaningful difference observed between the SST-6007 and topical placebo treatment groups. The concentration of sildenafil citrate detected in the blood after a single application of SST-6007 was significantly less than concentrations reported from oral administration of sildenafil citrate at comparable dose strengths. These data demonstrate

significant penetration of sildenafil citrate across the vulvar and vaginal epithelium, supporting a fast onset of action and 'on-demand' treatment indication for SST-6007.

About Female Sexual Arousal Disorder

Female sexual arousal disorder (FSAD) is characterized by a persistent or recurrent inability to attain or maintain sufficient sexual excitement or genital lubrication and swelling, causing personal distress. While FSAD can affect women of all ages, the prevalence of FSAD is primarily associated with vascular risk factors and menopause, with an estimated 40% of post-menopausal women experiencing difficulties with lubrication. Because there are currently no FDA-approved therapies available for the treatment of FSAD, topical lubricants and estrogen creams are often recommended to alleviate symptoms; unfortunately, however these remedies are often ineffective in treating women with an arousal disorder.

About SST-6007

SST-6007, 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 citrate, 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. Viagra® is available as a prescription drug for men with erectile dysfunction; 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 citrate preparation (i.e. SST-6006) for men with erectile dysfunction, which is currently in Phase 2 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, KNOSIS™ prevents the formation of hydrogen bonds between the API and the stratum corneum, which can inhibit the API from permeating 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 & 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

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