Strategic Science and Technologies LLC announces completion of its Phase 1 clinical trial for SST-6007, a first-in-class topical sildenafil cream, to treat female sexual arousal disorder

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- SST-6007 was well tolerated in healthy subjects, with no dermal irritation observed at clinically relevant doses
- SST-6007 successfully delivered sildenafil to the local target tissue
- SST-6007 was systemically absorbed into the bloodstream, but at significantly reduced levels compared to the marketed oral formulation of sildenafil (Viagra®)

CAMBRIDGE, Mass. – May 15, 2015 - Strategic Science and Technologies LLC (SST), a clinical-stage biotechnology company developing novel first-in-class topical formulations of known pharmaceutical products, announced today the successful completion of a Phase 1 clinical trial of SST-6007, the Company's first-in-class topical sildenafil product candidate in development for the treatment of female sexual arousal disorder (FSAD). The Phase 1 trial assessed the vulvar-vaginal safety, tolerability and pharmacokinetics of SST-6007 in healthy, post-menopausal women following application of a single dose.

"We are encouraged by these promising results in women, which further validate our KNOSIS™ platform and mark an important milestone for the treatment of FSAD," said Eric T. Fossel, Ph.D., Scientific Founder and Chief Executive Officer of SST. "We look forward to evaluating topical sildenafil in patients with the goal of commercializing a safe and effective, over-the-counter product that will positively impact sexual health in both men and women."

SST-6007 was found to be well tolerated by the healthy study subjects, 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 detected in the blood after a single application of SST-6007 was significantly less than concentrations reported from oral administration of sildenafil at comparable dose strengths. These data demonstrate significant penetration of sildenafil across the vulva and vaginal epithelium, and support SST's efforts to demonstrate that a single application of SST-6007 will deliver a therapeutic concentration of sildenafil to the local target tissue that is equal to or greater than that delivered from a single oral dose.

"These findings support the case for SST-6007 as a potential treatment for women with FSAD," commented Irwin Goldstein, M.D., Director of Sexual Medicine at Alvarado Hospital and Director of San Diego Sexual Medicine." With no FDA approved treatments available for women with desire, arousal or orgasm sexual dysfunctions, the development of potential products such as SST-6007 is an exciting initial step toward addressing this important unmet need, and I look forward to facilitating its development in future clinical studies."

SST intends to demonstrate in its development program that SST-6007 is a safe and effective treatment for women with female sexual arousal disorder. In addition, the very low systemic absorption of sildenafil from SST-6007 application, compared to the marketed oral formulation of sildenafil (Viagra®), offers the potential to significantly reduce the side effects long associated with oral phosphodiesterase type-5 (PDE-5) inhibitors.

About the SST-6007 Phase 1 Trial

The SST-6007 Phase 1 clinical trial was a single center, open-label, placebo-controlled, within-subject dose-escalation study design used to evaluate 3 dose levels of SST-6007 in healthy post-menopausal women. Doses, beginning with a placebo cream, were administered sequentially and separated by a two-week washout period. Safety assessments included physical and gynecological examination, clinical laboratory evaluations, ECG, and adverse events. Pharmacokinetic analyses to determine concentrations of sildenafil in the plasma were completed at pre-specified time points from pre-dose up to 32 hours post-dose.

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 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, 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; 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-6006) for men with erectile dysfunction, which has recently advanced to Phase II 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 and 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, diabetes, infectious disease, 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 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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