



VIVUS Announces Positive Phase 3 Clinical Trial Results for Evamist(TM) - The First Transdermal Spray for the Treatment of Menopausal Symptoms

Evamist, First Novel Transdermal Spray, Shows 78% Decrease in Moderate to Severe Hot Flashes

MOUNTAIN VIEW, Calif., May 5 /PRNewswire-FirstCall/ -- VIVUS, Inc. (Nasdaq: VVUS) today announced positive results from the pivotal Phase 3 clinical trial of Evamist™. VIVUS' investigational estradiol metered dose transdermal spray is being developed for the treatment of vasomotor symptoms associated with menopause. The study showed a statistically significant reduction in the number and severity of moderate and severe hot flashes for all three doses tested. Evamist is a novel, once a day proprietary, first-in-class, transdermal spray that delivers estradiol, a naturally occurring estrogen, for the treatment of hot flashes in women. Evamist is a small, hand-held, simple-to-use spray that is designed to provide an easy and convenient means to deliver a preset dose of estradiol via the skin. Evamist is fast drying, non-irritating and invisible after application. Studies have shown that once administered, Evamist's formulation is not affected by washing and does not transfer to partners. Evamist is easily titratable between one, two or three sprays.

VIVUS' Phase 3 study assessed the safety and efficacy of Evamist for the treatment of hot flashes in menopausal women. The Phase 3 trial, which was conducted at 43 clinical sites in the United States, was a 12-week, randomized, double-blind, placebo controlled study of 457 menopausal women. Patients were randomized into three treatment arms each administering a different dose with one, two or three sprays. This study was conducted under a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration (FDA). Results showed that the most effective Evamist dose significantly decreased the number of hot flashes by 78%, from 10.7 hot flashes per day at baseline to 2.3 hot flashes after treatment. This decrease was statistically significant compared to placebo ($p < 0.0001$). The reduction in frequency and severity of moderate to severe hot flashes was statistically significant over placebo for all three doses of Evamist evaluated. Importantly, application site irritation was less than 1% and was mild in nature.

"We believe these positive trial results along with our novel patient-preferred transdermal delivery system will establish Evamist as a superior estrogen therapy for the treatment of menopausal symptoms," stated Leland F. Wilson, president and chief executive officer for VIVUS. "We have worked diligently toward the development of this unique and easy-to-use product, and we are thrilled with the efficacy and safety demonstrated in this trial. We now look forward to filing an NDA for Evamist in the second half of 2006."

"These clinical results demonstrate Evamist's efficacy as a treatment option for the large population of women suffering from menopausal symptoms," stated Dr. John Buster, Professor, Baylor College of Medicine. "Symptoms of menopause can be devastating and debilitating. This data indicates that Evamist offers a valuable therapeutic option to this significant patient group."

About Evamist

VIVUS believes Evamist offers significant advantages over oral, gel and patch estrogen products. Evamist is a small, hand-held, simple to use spray that is designed to provide an easy and convenient means to deliver a preset dose of estradiol via the skin. Evamist is placed gently against the skin and an actuator button is pushed which releases a light spray containing a proprietary formulation of estradiol. Estradiol is released into the blood stream on a sustained basis over 24 hours. Evamist is fast drying, non-irritating and invisible after application.

About Menopause

Approximately two million American women turn 50 each year. Women naturally enter into menopause usually between the ages of 45 and 55; however, surgical menopause may happen at any age. Menopausal symptoms occur when the ovaries stop producing estrogen. Symptoms include hot flashes, discomfort or pain during sexual intercourse due to vaginal atrophy (thinning of the vagina), and changes in skin and hair.

About VIVUS

VIVUS, Inc. is a pioneer in the research and development of proprietary products to restore sexual function for women and men. VIVUS' current product pipeline includes four investigational products in late stage clinical development. For women,

VIVUS has completed a Phase 3 program for Evamist™ for the alleviation of menopausal symptoms, and initiated a Phase 2B program with ALISTA™ for female sexual arousal disorder. Additionally, the company has completed Phase 2 development of Testosterone MDTs® for the treatment of hypoactive sexual desire disorder (HSDD). The MDTs system is a patented new-generation, transdermal drug delivery technology that delivers drugs directly through the skin. For men, VIVUS has completed Phase 2 development of avanafil for erectile dysfunction. The company currently markets MUSE® (alprostadil) suppository for the treatment of erectile dysfunction in the U.S. and internationally through distributors. For more information on clinical trials and products, please visit the company's web site at www.vivus.com.

Note to Investors

VIVUS will hold an Analyst Day in New York City on Thursday, May 18, 2006, from 12:00 p.m. to 2:30 p.m. EDT. The event will be held at the Four Season's Hotel, 57 East 57th Street, New York, New York. VIVUS management and certain principal investigators will be on hand to discuss the results from the pivotal Phase 3 studies of Evamist. A detailed update on all other development programs as well as other corporate developments will be included. Seating is limited and participants can confirm their attendance by contacting Stephanie Diaz at Vida Communications, 415-675-7401 or sdiaz@vidallc.com.

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimated" and "intend," among others. These forward-looking statements are based on VIVUS' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; reliance on sole source suppliers; limited sales and marketing efforts and dependence upon third parties; risks related to the development of innovative products; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical studies discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. VIVUS does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2005 and periodic reports filed with the Securities and Exchange Commission.

SOURCE VIVUS, Inc.
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