

ENROLMENT COMPLETED IN US PHASE 3 TRIAL OF EVAMIST™ SPRAY FOR MENOPAUSE SYMPTOMS

Acrux's licensee for its lead product in the USA, VIVUS Inc. (Nasdaq: VVUS), today announced the completion of enrolment in its pivotal Phase 3 clinical study of Evamist™ (Estradiol MDTs®), an estradiol spray for the treatment of symptoms associated with menopause. VIVUS remains on track to submit a New Drug Application (NDA) for Evamist to the US Food and Drug Administration (FDA) in mid-2006.

This Phase 3 trial is a multi-centre, randomised, double-blind, placebo-controlled study to evaluate the safety and efficacy of Evamist. The primary endpoint is the reduction in the frequency and severity of moderate-to-severe vasomotor symptoms associated with menopause at weeks 4 and 12 of the study. Over 400 patients were enrolled at 43 centres throughout the USA.

The study was initiated in December 2004 under a Special Protocol Assessment (SPA) with the FDA. The SPA is a formal agreement that designates the agreed upon terms and conditions under which VIVUS will conduct and analyse the data from the Phase 3 trial. The SPA provides official confirmation from the FDA that the protocol design is sufficient for a Phase 3 trial which, if completed as agreed, can form the basis of the submission of a NDA that will include an efficacy label claim for Evamist for the relief of moderate to severe vasomotor symptoms associated with menopause.

Acrux CEO Igor Gonda commented "We are very pleased with the rapid progress that VIVUS is making towards completion of development and commercialisation of our first product for a large US market, further validating our technology and business model. Acrux retains the rights for this product for the rest of the world".

VIVUS Senior Vice President of Product and Corporate Development, Peter Tam said "We believe Evamist has the potential to provide a practical and convenient option for the millions of women seeking a better treatment option for their menopausal symptoms".

Contact:

Igor Gonda, CEO & Managing Director

Tel: +61 3 8379 0100

About Evamist

Evamist, an investigational drug, is a small, hand-held, easy-to-use spray that is designed to provide an easy and convenient means to deliver a preset dose of estradiol via the skin. The Evamist applicator is placed gently against the skin and an actuator button is pushed. A light spray containing a proprietary formulation of estradiol is then released, where it is absorbed into the skin. This method of delivery eliminates the requirement to touch the formulation, and may decrease the transfer of the active ingredient to other areas of the body or to other persons. Estradiol is released into the blood stream on a sustained basis over 24 hours, providing a practical and convenient once-a-day dosing regimen. Evamist is believed to be the first transdermal estradiol spray delivery system under development in the USA. Evamist is fast drying, non-irritating and invisible after application. VIVUS licensed Evamist for the US market from Acrux in February 2004.

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 flushes, discomfort or pain during sexual intercourse due to vaginal atrophy (thinning of the vagina), and changes in skin and hair.

About Acrux

www.acrux.com.au

- Acrux is a specialty pharmaceutical company, developing and commercialising a range of patented, patient-preferred healthcare products for global markets, using its innovative technology to administer drugs through the skin.
- Acrux's product pipeline includes treatments of hormonal deficiencies, pain, central nervous system disorders and a contraceptive. 19 human clinical trials have been completed with 7 different drugs and the lead product, Evamist™, is currently in a phase 3 trial in the USA.
- Acrux has licensed USA rights for Evamist™ (Estradiol MDTs®) and Testosterone MDTs® to VIVUS and AUS/NZ distribution rights for Testosterone MDTs® and Fentanyl MDTs® to CSL Limited. Acrux has also licensed its technology to Eli Lilly for veterinary healthcare products.