

POSITIVE RESULTS FOR ACRUX'S LEAD PRODUCT IN US PHASE 3 TRIAL

- **Pivotal milestone for Evamist™ and Acrux's platform technology**
- **US marketing application to be submitted to FDA by Acrux's partner VIVUS in second half of 2006**
- **VIVUS to pay Acrux US\$4 million on submission and approval of marketing application, followed by royalties on sales**
- **Annual sales of estrogen-alone therapies in USA \$1.4 billion**

Melbourne, 8 May 2006: Acrux (ASX: ACR), the pharmaceutical company with unique technology for delivering drugs through the skin, today announced positive results in a US Phase 3 clinical trial of Evamist™, its daily skin spray for prevention of symptoms associated with menopause. The trial was conducted by its US commercial partner VIVUS Inc. (NASDAQ: VVUS), which will now proceed to file a marketing application with the US Food and Drug Administration (FDA) in the second half of 2006.

Evamist is the most advanced commercial application of Acrux's patented delivery technology; if the FDA approves VIVUS' marketing application, Acrux's first product could be available to women in the USA in the second half of 2007. Several other products that use the same delivery technology are following close behind. The positive result of this Phase 3 trial is therefore a pivotal milestone for each of these products.

The Phase 3 trial assessed the safety and efficacy of Evamist for the treatment of hot flashes in menopausal women. The trial was a 12-week study of 457 menopausal women, conducted under a Special Protocol Assessment (SPA) from the FDA. Results showed that the most effective Evamist dose decreased the number of hot flashes by 78%. The reduction in frequency and severity of moderate to severe hot flashes was statistically significant compared with placebo for all three doses of Evamist evaluated.

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Importantly, application site irritation was less than 1% and was mild in nature. The results from the trial will be discussed by VIVUS at an Analyst Day in New York on 18 May 2006.

“We believe these positive trial results along with this novel patient-preferred transdermal delivery system will establish Evamist as a superior estrogen therapy for the treatment of menopausal symptoms,” stated Leland 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.”

Professor Alastair MacLennan, Joint Editor-in-Chief of Climacteric, the Journal of the International Menopause Society, and a member of Acrux’s Scientific Advisory Board, commented “Evamist could provide an attractive new option for millions of women - a low dose estrogen, delivered in a simpler and more convenient way. These Phase 3 trial results demonstrate its efficacy in treating the key symptoms that may be suffered by this significant patient group”.

Acrux’s partnership with VIVUS

VIVUS licensed Evamist for the US market from Acrux in February 2004. VIVUS paid Acrux a licence fee of US\$1 million and will make further payments to Acrux totalling US\$4 million on filing and approval by the FDA of the US marketing application. VIVUS is responsible for manufacturing, sales and marketing in the USA and will pay Acrux royalties on sales. Acrux retains rights for the rest of the world and is seeking commercial partners for major markets, including Europe.

Menopause and Evamist

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. Annual sales of estrogen-only replacement therapies in the USA are estimated to be approximately US\$1.4 billion. Sales have now resumed growth after a period of decline, as new data from the Women’s Health Initiative study

showed that estrogen-alone therapy resulted in no increased risk of coronary heart disease or breast cancer. Transdermal estrogen patches and gels currently sell approximately US\$0.3 billion per annum. Primary market research studies suggest that many women would prefer to use Evamist over patches, gels and tablets.

Evamist, like Acrux's other women's health products addressing contraception and decreased libido, 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, a naturally occurring estrogen, 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, providing a practical and convenient once-a-day dosing regimen. 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 and three sprays.

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.
- Fast-drying, invisible sprays or liquids provide a delivery platform with low or no skin irritation, superior cosmetic acceptability and simple, accurate and flexible dosing. The technology platform is covered by broad and well-differentiated patents issued and pending in major markets.
- Acrux has 7 products in clinical development, including:
 - **Evamist™** to treat menopause symptoms
 - **Testosterone MDTS®** to treat decreased libido in women
 - **Nestorone® MDTS®** contraceptive spray for women
 - **Fentanyl UDTS™** to treat chronic pain
 - **Testosterone MD-Lotion®** to treat testosterone deficiency in men
- Acrux has licensed USA rights for Evamist™ (Estradiol MDTS®) and Testosterone MDTS® to VIVUS and AUS/NZ distribution rights for Testosterone MDTS® and Fentanyl UDTS™ to CSL Limited. Acrux has also licensed its technology to Lilly for veterinary healthcare products.

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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.

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Appendix 1 – Trial details

Name of trial	A Phase 3 Multi-Centre, Randomised, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Estradiol Metered-Dose Transdermal Spray (Evamist) in the Treatment of Vasomotor Symptoms in Postmenopausal Women
Treatment method, route, frequency, dose levels	Daily application to the skin of either one, two, or three sprays of Evamist for 12 weeks
Number of trial subjects	457 subjects at 43 clinical sites in the USA
Subject selection criteria	Postmenopausal women with a mean total frequency of ≥ 56 moderate to severe hot flashes per week
Control group	Daily application to the skin of either one, two, or three sprays of placebo for 12 weeks
Primary endpoint(s) results:	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. The decrease was statistically significant compared with 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.
Safety and tolerability	Application site irritation was less than 1% and was mild in nature