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ACRUX'S U.S. PARTNER, VIVUS, INITIATES PHASE 3 STUDY FOR EVAMIST™ (ESTRADIOL MDTs®)

Melbourne, 21 December 2004: Acrux Limited (ASX: ACR) announced today that its US partner, VIVUS Inc (NASDAQ: VVUS), is starting the pivotal Phase 3 clinical efficacy study for the treatment of menopausal symptoms with the transdermal spray product Evamist™ (Estradiol MDTs®).

VIVUS licensed Evamist™ (Estradiol MDTs®) for the US market from Acrux in February 2004. Under the terms of the agreement, Acrux will receive from VIVUS a licence fee of US\$1.0 million on or before 29 June 2005, and further payments of up to US\$4.0 million on filing and approval of the US New Drug Application (NDA). Acrux will receive royalties from VIVUS on net sales in the United States upon commercialisation of the product. VIVUS is responsible for funding the remaining development, including the Phase 3 trial. Acrux retains rights for the rest of the world and will be seeking commercial partners for such territories, including Europe.

The Phase 3 trial is a multi-centre, randomized, double-blind, multi-dose, placebo controlled study designed to evaluate the safety and efficacy of once-daily use of the Evamist™ spray. The primary endpoint in the 12 week treatment period will be to evaluate the reduction at weeks 4 and 12 in both frequency and severity of moderate-to-severe vasomotor symptoms (hot flushes) associated with menopause. This study aims to enrol 400-500 patients at approximately 40 centres in the USA. The completion of this study is expected in the second half of the 2005 calendar year with a view to NDA filing in the first half of 2006.

The US Food and Drug Administration (FDA) recently completed a Special Protocol Assessment (SPA) on the design of this pivotal Phase 3 clinical trial. The SPA provides guidance from the FDA on the study protocol design that is sufficient for a Phase 3 trial which can form the basis of the submission of a NDA for Evamist™.

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VIVUS President and CEO, Mr Leland Wilson said: "Evamist is a patented new-generation of transdermal spray delivery. We believe Evamist has the potential to provide women relief from menopausal symptoms such as hot flushes and can do so in a discrete and convenient manner".

Acrux CEO and Managing Director, Dr Igor Gonda said: "The initiation of this pivotal study marks the last stage of development for Evamist and is the most significant step for bringing to the large US market our first therapeutic product in a suite of innovative products for women's health".

The global market for estrogen therapy is valued at US\$1.1 billion (IMS Health, IMS Midas, MAT Oct 2004). The number of post-menopausal women in the USA is estimated in excess of 40 million women and combined populations of post-menopausal women in leading European markets at 50 million (Reuters, 2003, *The Women's Health Outlook to 2008*).

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Background Information:

EvamistTM

Evamist is an investigational drug that has not been approved yet by the FDA or any other regulatory authority. 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, providing a practical and convenient once-a-day dosing regimen. Evamist is fast drying, non-irritating and invisible after application.

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About Acrux

- Acrux Limited's group of companies is engaged in the development and commercialisation of a range of patented, patient-preferred healthcare products for global markets.
- Acrux has completed fourteen human clinical trials with 6 different drugs using its proprietary drug delivery technology, comprising ACROSS[®] penetration enhancers, Metered Dose Transdermal System (MDTS[®]) applicators for transdermal administration and Patchless Patch[®] delivery method.
- Acrux's portfolio includes treatments of hormonal deficiencies, pain, central nervous system disorders and urinary incontinence, as well as a contraceptive.
- Acrux has licensed USA rights to its two lead products, 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 for commercial development to **Eli Lilly** for veterinary healthcare products, and to Connetics Australia, a subsidiary of the US Company **Connetics**, for anti-psoriatics and local anaesthetics.

About VIVUS, Inc

VIVUS Inc. is a pioneer in the research and development of proprietary products to restore sexual function for men and women. VIVUS' current product pipeline includes four products in late stage clinical development. For women, VIVUS has initiated its Phase 3 programs with ALISTA[™] for female sexual arousal disorder, and Evamist for the alleviation of menopausal symptoms. VIVUS anticipates entering into Phase 3 studies with Testosterone MDTS[®] for the treatment of sexual desire disorder in 2005. The MDTS system is a patented new-generation, transdermal drug delivery technology that delivers drugs through the skin. For men, VIVUS is developing avanafil for erectile dysfunction, which is currently in a Phase 2 program. VIVUS currently markets MUSE[®] (alprostadil) suppository in the US for the treatment of erectile dysfunction. For more information on clinical trials, products and corporate goals, please visit the Company's web site at www.vivus.com.

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