ACRUX Press Release

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# CLINICAL TRIAL OF THE WORLD'S FIRST CONTRACEPTIVE SPRAY FOR WOMEN - ACRUX AND POPULATION COUNCIL ANNOUNCE POSITIVE DATA

**Melbourne 20 June 2005:** The Population Council Inc, an international research organisation based in New York, and Acrux Limited (ASX: ACR), the Australian pharmaceutical company which specialises in administering drugs through the skin, today announced positive results from the first clinical study of a novel contraceptive spray for women.

The study was a Phase I, Proof-of-Concept, pharmacokinetic study, conducted in six healthy women. The results showed that once-a-day dosing of the contraceptive spray Nestorone MDTS® provided sustained delivery of the contraceptive agent, Nestorone®. Mean serum concentrations of Nestorone® were maintained in the target range expected to be effective for contraception. The spray was well tolerated, with no serious adverse events recorded. Full details of the study are presented in Appendix 1.

The trial results were presented at BIO 2005 in Philadelphia by Dr Igor Gonda, CEO of Acrux Limited. Dr Regine Sitruk-Ware, executive director of product research and development at the Population Council's Center for Biomedical Research, New York, noted that potential advantages of Nestorone MDTS® over existing methods of contraception, such as pills and patches, are

- suitability for breast feeding mothers and women who cannot tolerate combined oral contraceptives containing oestrogens
- increased flexibility in dosing time compared to progestogen-only pills
- reduced skin irritation compared to patches
- convenient daily dosing of the spray which leaves no visible residue on the skin.

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Dr Gonda said "Nestorone MDTS is another product in our women's health portfolio delivered as a daily spray. We believe that many women will prefer this method. Our transdermal sprays are easy to use and would eliminate the need to swallow pills, take injections, or wear patches."

The clinical study was sponsored by FemPharm Pty Ltd., a wholly owned subsidiary of Acrux Limited. Principal Investigators were Professor Ian Fraser, AO, Professor in Reproductive Medicine at the University of Sydney, Australia and Dr Edith Weisberg, Director of Research, Sydney Centre for Reproductive Health Research, Research Division of FPA Health, Sydney, Australia.

The study was carried out under a joint development agreement between the Population Council and FemPharm on the transdermal spray delivery of the Population Council's Nestorone®, a fourth-generation progestin which is not absorbed when administered by mouth. Acrux's patented transdermal delivery system, MDTS®, applies a pre-set dose of fast-drying formulation on the skin. This forms an invisible depot within the skin from which Nestorone® is slowly absorbed into the bloodstream.

The clinical study completes the primary obligations of the Population Council and FemPharm under the joint development agreement. The parties are currently negotiating an agreement under which FemPharm will obtain a licence to use Nestorone® with its MDTS® system.

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**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 urinary incontinence, as well as a contraceptive.
- 17 human clinical trials have been completed with 7 different drugs and the lead product, Evamist™ (Estradiol MDTS®), is currently in a phase 3 clinical 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, to **Napa Biosciences** for certain dermatology products and to **Connetics** for anti-psoriatics and local anaesthetics.

**About the Population Council**

- The Population Council, an international, non-profit, non-governmental organisation, seeks to improve the well-being and reproductive health of current and future generations around the world to help achieve a humane, equitable, and sustainable balance between people and resources. The Population Council conducts biomedical, social science, and public health research and helps build research capacities in developing countries. Established in 1952, the Council is governed by an international board of trustees. Its New York headquarters supports a global network of regional and country offices.
- The Population Council has a proven track record in the successful development of female contraceptive products and has worked to make them accessible to people in developing countries. Three of the four major long-lasting reversible contraceptives available today were developed by the Population Council: the Copper T IUD, Norplant®, and Mirena®. More than 50 million Copper T IUDs have been distributed in over 70 countries.

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**Appendix 1 – Trial Details**

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|---|---|
| Name of trial | A phase I study to determine the pharmacokinetics of Nestorone® delivered with the Metered Dose Transdermal System (MDTS®) in postmenopausal women. |
| Blinding status | Unblinded. |
| Treatment method, route, frequency, dose levels | In period 1 of the study, subjects were given three sprays of Nestorone MTDS® as a single dose to the forearm.<br><br>In period 2 of the study, the same subjects were given three sprays of Nestorone MDTS® each day for five days. Application was to the forearm. |
| Number of trial subjects | Six subjects participated in and completed the study. |
| Dropout rate | There were no dropouts. |
| Subject selection criteria | The selection criteria were healthy, post menopausal women, aged 45-60. The actual subjects' ages ranged from 48-59 years. |
| Control group | This study did not include a control group. |
| Primary endpoint(s) results: | Single dose application of the Nestorone MDTS® to the forearm in period 1 of the study indicated successful transdermal absorption, and justification for continuing into period 2 of the study.<br><br>In period 2 of the study, daily dosing of Nestorone MDTS® for five days produced average serum concentrations at steady state within the therapeutic range required for contraceptive purposes. |
| Safety and tolerability | No serious adverse events were recorded.<br><br>A total of twenty five adverse events were reported during the study, all of which were classified as either mild or moderate in severity. Sixteen of these were deemed not to be related to the administration of Nestorone MDTS®. The remaining nine events were all mild and five of these were experienced by one subject.<br><br>There were no incidences of skin irritation at the application site that were deemed related to the Nestorone MDTS®. |

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