

AUSTRALIAN KNOW-HOW BOOSTS WOMEN'S SEXUAL SATISFACTION

Melbourne, 10 February 2005: A unique testosterone skin spray invented in Australia has significantly improved younger women's enjoyment of sex in a well controlled clinical trial conducted in Australia.

“Many young women report having low sexual interest and sexual enjoyment and that this is troublesome for them. Traditionally this has been explained away as being caused by relationship issues, depression or other life circumstances. However we now know that for many women the underlying problem is biological.” says Professor Susan Davis who was principal investigator of this trial.

“Also, most of the research done to date has involved women who have already passed through the menopause, but lots of younger women have problems which are not solved with counselling or lifestyle changes. A proportion of such younger women have low blood testosterone levels. We have shown in this study that by restoring testosterone hormone levels back to normal, women's sexual lives are restored as well, to a significant extent” said Professor Davis.

The findings being released today are from a study of the hormone testosterone, delivered via unique patented Australian technology, invented originally at the Victorian College of Pharmacy, Monash University in Melbourne; a special skin spray which delivers both testosterone and a substance to ensure the testosterone is held in the skin and absorbed over a 24 hour period. This is very much like the way a patch can be used to deliver a drug via the skin surface, but without the patch. In fact the developers, Acrux, a Melbourne-based Australian company, call it a “Patchless Patch[®]”. This new product is called Testosterone MDTs[®] (metered dose transdermal spray).

The Phase 2 study was part of the drug approval process for the US Food and Drug Administration (FDA), and researchers investigated several doses to determine which dose provides the best effect. The trial was a randomised, double-blind, placebo controlled study in 261 premenopausal women who were troubled by low libido and who also had low serum testosterone levels. It was conducted at 6 sites across Australia, with a once-daily administration of the Acrux's product Testosterone MDTs[®] to the abdomen over a 16 week treatment period.

Three different doses were studied and compared with a placebo or inactive dose. Each woman recorded all sexual events in a diary along with the level of satisfaction she experienced with each event. The effectiveness of treatment was pre-defined as whether treated women reported a statistically significant greater number of satisfactory sexual events over the last 4 weeks of treatment (week 12 to 16) compared with women treated with placebo.

“People worry about side effects of testosterone in women. However it is important to note that testosterone is an essential female hormone and healthy young women normally have much more testosterone circulating in their blood at any given moment than estrogen. In this study few side effects were documented with Acrux’s Testosterone MDTS.” said Dr Davis, who is Professor of Women’s Health in the Department of Medicine at Monash University and a consultant endocrinologist at the Alfred Hospital, Melbourne. “We observed slight hair growth in some women and there was little or no skin irritation.”

“The next step before approval by the regulatory authorities will be Phase 3 studies to confirm the effectiveness and safety of this new therapy in greater number of women over a longer period of time. These are being planned for USA with Acrux’s US partner VIVUS Inc. If further studies reconfirm the benefits we have just seen, then the Testosterone MDTS[®] could make an enormous difference to the quality of many women’s lives.”

Background

The Technology

Skin or “transdermal” delivery via gels, patches and creams has been one of the most popular alternatives to pills and capsules. The vast majority of transdermal drug delivery systems rely upon the addition of chemical penetration enhancers to passively improve the transport of drugs through the skin. Acrux’s ACROSS[®] enhancers fall within this category. The MDTS[®] is a small and easy to use drug delivery system containing a therapeutic drug and the ACROSS[®] enhancers. It provides a simple way of applying a pre-set dose of a drug to the skin. The MDTS[®] applicator is placed gently against the skin and depressed releasing a light spray which quickly dries on the skin. The ACROSS[®] enhancers allow the drug to pass through the top layers of the skin, forming an invisible reservoir of the drug and enhancer within the skin.

The study

This is the first report on low libido treatment in premenopausal women in a study done in support of a New Drug Application (NDA) and following guidance from the U.S. Food and Drug Administration (FDA). This study sponsored by Acrux completed the Phase 2 program and after this, for the US market, there is the last stage of clinical trials called Phase 3. Acrux’s US partner VIVUS has a goal of starting the Phase 3 studies this year. There is no target date for approval yet.

For further information regarding testosterone in women

see the Monash Women’s Health Program Website:

<http://www.med.monash.edu.au/medicine/alfred/womenshealth/>

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