FDA ADVISORY COMMITTEE MEETING ON TESTOSTERONE REPLACEMENT THERAPY

Acrux (ASX: ACR) confirmed today that on September 17th 2014 (US time), the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee and its Drug Safety and Risk Management Advisory Committee met to discuss the appropriate population for testosterone replacement therapy and the potential for adverse cardiovascular outcomes.

The FDA convenes Advisory Committees for multiple purposes, particularly to gain expert insight on the review of new products, issues covering products across different therapeutic areas, device-related question and policy-related questions.

The Panel reviewed all available data and concluded that there is insufficient evidence that testosterone use leads to an increased risk of cardiovascular events. The Panel further recognised that there are no large studies available that were designed to specifically address the question, and recommended that companies be required to conduct additional studies to assess the cardiovascular risk of their products for patients with age-related low testosterone.

In this regard, the results of several studies are expected in the next six months, including Lilly's own study known as TSAT, and three studies funded by the National Institutes of Health. The Lilly study will evaluate the impact of testosterone on energy level and sexual arousal, interest and drive, as well as the safety of testosterone. Though not designed specifically to assess the risk of cardiovascular events, this study will collect information on any cardiovascular events that occur during the study. The study was initiated early 2013 and last patient visit of the double-blind phase is scheduled to be completed in October 2014. More information about this study can be found on clinicaltrials.gov.

The FDA also asked the advisory panel to consider the current indication for testosterone therapies. The panel voted in favour of changing language in the products' labels to restrict the intended uses of the drugs, particularly in relation to age-related low testosterone.

According to an FDA analysis, 21% of patients prescribed testosterone did not appear to have their testosterone concentrations tested before or during treatment. Prior to starting therapy, existing Endocrine Society Clinical Practice Guidelines recommend that health care practitioners measure morning testosterone levels as the initial diagnostic test and confirm the diagnosis by repeating the test. The guidelines then recommend monitoring patient's testosterone concentration three to six months after initiation of treatment and then annually to assess response to treatment. Lilly encourages physicians to check testosterone levels during therapy and to monitor treatment as outlined by these guidelines, which are consistent with the Axiron product label.

The FDA is not obliged to follow the advice of its advisory panels. It is premature to speculate how the FDA will consider the Committee's recommendation today, and whether the prescribing physicians will change their prescribing habits if any labelling changes are required by the FDA.

Contact

Ross Dobinson, Executive Chairman: 03 9691 5920

About Acrux www.acrux.com.au

- Acrux is an Australian drug delivery company, developing and commercialising a range of patient-preferred, patented pharmaceutical products for global markets, using its innovative technology to administer drugs through the skin.
- The Acrux technology, used in marketed products including Axiron®, Evamist® and Recuvyra™, is based on a fast-drying, small volume, accurately dosed solution, containing penetration enhancers, that when applied topically, deposit drug through the skin for long acting delivery.
- Acrux has three products marketed by licensees in the USA, three products approved in Europe, and further products at earlier stages of development.