Lilly to Acquire Global License to AXIRON Testosterone Solution From Acrux

AXIRON NDA currently under review by U.S. FDA for the treatment of testosterone deficiency in men

INDIANAPOLIS and MELBOURNE, Australia, March 15, 2010 /PRNewswire via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) and Acrux (ASX: ACR) announced today that they have entered into an exclusive worldwide license agreement for the potential commercialization of Acrux's experimental underarm testosterone solution (proposed tradename AXIRON(TM)). The new drug application for AXIRON is currently under regulatory review by the U.S. Food and Drug Administration (FDA) for the treatment of testosterone deficiency (hypogonadism) in men.

Under the terms of the agreement, Lilly will receive exclusive worldwide rights to commercialize AXIRON. In exchange for these rights, Acrux will receive an upfront payment of $50 million plus $3 million on the transfer of manufacturing assets. Acrux is further eligible for $87 million upon the issuance of marketing authorization by the FDA, and up to $195 million in potential commercialization milestones, as well as royalty payments on future global sales if AXIRON is successfully commercialized. (All financial terms are denominated in U.S. dollars) As a result of this transaction, Lilly expects to incur a charge to earnings in the first quarter of 2010 of approximately $.03 per share.

"The addition of AXIRON reinforces Lilly's commitment to men's health and, if approved, could provide a new treatment option for men suffering from low testosterone," said Bryce Carmine, president of Lilly's Bio-Medicines. "Lilly hopes to leverage our experience in men's health to advance both the science and clinical outcomes for men with low testosterone. Some of the needs of patients in approaching therapy include the need for a convenient way to administer therapy over a small and discreet area of the body. AXIRON has the potential to be the first testosterone solution to be applied via an underarm applicator, for patients who have testosterone deficiency. We look forward to working with Acrux and the FDA during the regulatory review process."

"We are delighted to build on our established relationship with Lilly and collaborate on the potential worldwide commercialization of AXIRON," said Dr Richard Treagus, chief executive officer of Acrux. "Through Lilly's considerable global resources and leadership position in the field of men's health, Acrux now has the opportunity to achieve the full commercial potential of AXIRON."

About Hypogonadism

Testosterone deficiency in men (hypogonadism) is associated with a number of clinical problems. It has been estimated that up to 39% of men over 45 years of age may have testosterone levels below the normal healthy range(1). However, in the majority of men this remains undiagnosed, with approximately 10% of those with the condition receiving treatment(1). According to IMS data, global sales of testosterone therapies have grown to more than $1 billion per year, with sales of testosterone gels in the US comprising $700 million.

AXIRON is an unregistered medicine in Australia.

About Acrux

Acrux is an Australian drug delivery company, developing and commercializing a range of patented pharmaceutical products for global markets, using its innovative technology to administer drugs through the skin. Additional information about Acrux is available at www.acrux.com.au.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com. C-LLY

This press release contains forward-looking statements that are based on Lilly's current expectations, but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products (including the compound discussed in this press

release) that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. For additional information about the factors that affect the company's business, please see Lilly's latest Form 10-K, filed February 2010. The company undertakes no duty to update forward-looking statements.

(1) Mulligan T; Frick M; Zuraw Q; Stemhagen A; McWhirter C. Prevalence of Hypogonadism in Males Aged at Least 45 Years: the HIM Study. Int J Clin Pract 60(7):762-769, 2006.

SOURCE Eli Lilly and Company