Lilly and Acrux Receive FDA Approval for Axiron® (Testosterone) Topical Solution CIII

Axiron is the first approved testosterone replacement therapy applied to the underarm

INDIANAPOLIS, Ind. and MELBOURNE, Australia, Nov. 23, 2010 /PRNewswire-FirstCall/ -- Eli Lilly and Company (NYSE: LLY) and Acrux (ASX: ACR) announced that the U.S. Food and Drug Administration (FDA) has approved Axiron® (testosterone) topical solution CIII for replacement therapy in men for certain conditions associated with a deficiency or absence of testosterone. Safety and efficacy of Axiron in males younger than 18 years of age have not been established.

To view the multimedia assets associated with this release, please click: http://multivu.prnewswire.com/mnr/lilly/47456/

Axiron is the first testosterone topical solution approved for application via an armpit (underarm) applicator. Other forms of testosterone replacement therapy include: oral tablets, buccal tablets, subcutaneous pellets, transdermal patches, injections and topical gels applied by the hands.

Although the total number of men with testosterone deficiency is unknown, it has been estimated that up to 13 million men over 45 years of age in the U.S. may have symptoms associated with low testosterone.(1) Clinical trial data indicated that Axiron can restore blood concentration of testosterone within the normal range in most men.(2)

"Lilly is proud to expand our focus in men's health," said David Ricks, president, Lilly USA. "The addition of Axiron to our product portfolio reinforces Lilly's commitment to provide innovative treatment options for patients."

"The FDA approval is a major milestone for Axiron and for Acrux," said Dr. Richard Treagus, chief executive officer, Acrux. "After years of research, we are excited to partner with Lilly to provide this novel application method for men with low testosterone."

About Testosterone Deficiency

Testosterone deficiency is a clinical condition in which the testicles, hypothalamus or pituitary gland is affected by disease or damage that results in inhibiting hormone secretion and testosterone production.(3) Testosterone deficiency also may be known as hypogonadism or low testosterone. Signs/symptoms associated with male hypogonadism include erectile dysfunction and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics and osteoporosis.(2)

About the Axiron Phase III Study

The data submission package for Axiron included findings from a Phase III multi-center, open label, 120-day clinical study which demonstrated that 84 percent of men who completed the study achieved average serum testosterone concentration within the normal range of 300-1050 ng/dL. Additionally, after 120 days of treatment, 75 percent of responding patients finished the study on the recommended starting dose of 60 mg.(2)

The most common adverse reactions (incidence>4%) in this Phase III study were skin application site reactions, increased red blood cell count, headache, diarrhea, vomiting and an increase in blood level of Prostate Specific Antigen (a test used to screen for prostate cancer).(2)

About Axiron (testosterone) topical solution

Axiron is approved for replacement therapy in men for certain conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired). Safety and efficacy of Axiron in males younger than 18 years of age have not been established. Axiron contains testosterone, a Schedule III controlled substance as defined by the Anabolic Steroid Control Act of 2004 and can be a target for people who abuse prescription medicines. Patients should keep Axiron in a safe place to protect it. Never give it to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and is against the law.

Axiron is a topical, alcohol-based testosterone solution applied to the underarm once daily using a metered dose applicator. The recommended starting dose is 60 mg applied once daily, preferably at the same time each morning. Patients who use antiperspirant or deodorant should apply it before using Axiron to avoid contamination of the deodorant.(2)

Important Safety Information for Axiron

WARNING: SECONDARY EXPOSURE TO TESTOSTERONE

- **Virilization has been reported in children who were secondarily exposed to topical testosterone products**
- **Children should avoid contact with unwashed or unclothed application sites in men using Axiron**
- **Healthcare providers should advise patients to strictly adhere to recommended instructions for use**

Axiron can transfer from your body to others. This can happen if other people come into contact with the area where Axiron was applied. Signs of puberty that are not expected (for example, pubic hair) have happened in young children who were accidentally exposed to testosterone through skin-to-skin contact with men using topical testosterone products like Axiron. Women and children should avoid contact with the unwashed or unclothed area where Axiron has been applied. If a woman or child makes contact with the application area, the contact area on the woman or child should be washed well with soap and water right away.

To lower the risk of transfer of Axiron from your body to others, you should follow these important instructions. Apply Axiron using the applicator only to your armpits, wash your hands right away with soap and water after applying Axiron. After the solution has dried, cover the application area with clothing. Keep the area covered until you have washed the application area well or have showered. If you expect another person to have direct skin-to-skin contact with your armpits, first wash the application area well with soap and water.

Stop using Axiron and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have occurred through accidental exposure to Axiron. Signs and symptoms in children may include an enlarged penis or clitoris; early development of pubic hair; increased erections or sex drive; aggressive behavior. Signs and symptoms in women may include changes in body hair and a large increase in acne.

Who should not use Axiron

Do not use Axiron if you have or might have prostate cancer, have breast cancer, are pregnant or may become pregnant or are breast-feeding. Axiron may harm your unborn or breast-feeding baby. Women who are pregnant or who may become pregnant should avoid contact with the area of skin where Axiron has been applied.

What men should tell their healthcare provider before using Axiron

Before you use Axiron, tell your healthcare provider about all your medical conditions, especially if you have breast cancer, have or might have prostate cancer, urinary problems due to an enlarged prostate, heart problems, kidney or liver problems or problems breathing while you sleep (sleep apnea).

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Using Axiron with other medicines can affect each other. Especially, tell your healthcare provider if you take insulin, medicines that decrease blood clotting or corticosteroids.

What are the possible side effects of Axiron

Axiron can cause serious side effects. If you already have enlargement of your prostate gland, your signs and symptoms can get worse while using Axiron. There is a possible increased risk of prostate cancer. Your healthcare provider should check for prostate cancer or any other prostate problems before you start and while you use Axiron. In large doses Axiron may lower your sperm count. You may experience swelling of your ankles, feet or body, enlarged or painful breasts, problems breathing while you sleep (sleep apnea) or blood clots in the legs (which could include pain, swelling or redness). Stop using Axiron and call your healthcare provider right away if you have any of the serious side effects listed above.

The most common adverse reactions were skin redness or irritation where Axiron is applied, increased red blood cell count, headache, diarrhea, vomiting and increase in blood level of Prostate Specific Antigen (a test used to screen for prostate cancer). Other side effects include more erections than are normal for you or erections that last a long time.

Axiron is flammable until dry. Let Axiron dry before smoking or going near an open flame.

For additional safety information, please see the medication guide at http://pi.lilly.com/us/axiron-medguide.pdf or full Prescribing Information, including Boxed Warning, at http://pi.lilly.com/us/axiron-pi.pdf.

About the Acrux and Eli Lilly and Company Partnership

Upon FDA approval, Lilly received exclusive worldwide rights to commercialize Axiron. In exchange for these rights, Acrux receives 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).

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.

This press release contains forward-looking statements about the potential of Axiron for replacement therapy in men for certain conditions associated with a deficiency or absence of testosterone, and reflects Lilly's current beliefs. Safety and efficacy of Axiron in males younger than 18 years of age have not been established. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that the product will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's Form 10-K dated February 2010 and Form 10-Q dated October 2010 filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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(1) Mulligan, T., Frick, M., Zuraw, Q., Stemhagen, A. and McWhirter, C. Prevalence of Hypogonadism in Males Aged at Least 45 Years; The HIM Study. International Journal of Clinical Practice. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1569444/. Last accessed on November 14, 2010.

(2) Axiron Prescribing Information. Last accessed on November 23, 2010.

(3) Winters, S. Current Status of Testosterone Replacement in Men. Archives of Family Medicine. 1999;8:257-263. Available at http://archfami.ama-assn.org/cgi/content/full/8/3/257. Last accessed on November 14, 2010.

SOURCE Eli Lilly and Company