AXIRON® LICENSE AGREEMENT TERMINATED

Melbourne, Australia – Acrux (ASX:ACR) has today announced that Acrux and Eli Lilly and Company have mutually agreed to terminate their licensing agreement for Axiron®. Termination of the license in the US is effective immediately and termination of license outside the US will be effective 90 days thereafter. Global rights to the product will revert to Acrux.

Following an Advisory Committee meeting in 2014, the US Food and Drug Administration (FDA) required holders of new drug applications (NDAs) for approved testosterone products to conduct a well-designed Postmarketing Requirement (PMR) clinical trial to more clearly address the question of whether an increased risk of heart attack or stroke exists among users of testosterone products. The trial would need to be conducted independently or through a consortium of NDA holders. The FDA requires a submission of the final PMR protocol by 5 September 2017. In the absence of a commitment to the PMR protocol, the FDA may take regulatory action against an NDA holder.

On 23 August 2016, Acrux, and its licensee Eli Lilly and Company, appealed the decision by the United States District Court for the Southern District of Indiana, in which the Axiron® formulation and axilla application patents granted by the US Patent and Trademark Office were held invalid. The Court of Appeals for the Federal Circuit in Washington, DC has scheduled the Axiron® patents appeal proceedings for 5 October 2017. Acrux anticipates a decision from Federal Circuit within 6 months. Generic versions of Axiron® were launched in the US by Perrigo and Teva in July and August 2017 respectively, along with an Authorized Generic marketed by Prasco.

With the commercial uncertainty related to the impact of generics, the continued decline in the testosterone market, and the uncertain apportioned costs to participate in the PMR consortium of testosterone NDA holders, a request will be submitted to FDA to withdraw the NDA from the US market.

Acrux continues to believe that the Axiron® axilla application patent is valid and enforceable, and Acrux is committed to asserting its intellectual property rights for Axiron®. The Appeal proceedings scheduled for 5 October 2017 will continue. Acrux and Lilly continue to stand by the safety and efficacy of Axiron® when used as indicated.

For further information, contact

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About Acrux

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising specialty and generic topical pharmaceuticals. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and commercialised through licensees a number of pharmaceutical products in the US and Europe using the Patchless Patch™, a fast-drying and invisible topical application technology. Marketed products include Axiron®, Evamist® and Lenzetto®. More recently, in addition to specialty products, Acrux has identified and initiated development of a range of generic products. Acrux is leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring more products to market. Acrux encourages collaboration and is well positioned to discuss partnering and product development.

For further information on Acrux, visit www.acrux.com.au