ASX/Media Release

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Acrux submits application for generic testosterone topical solution with US$139 million addressable market size[1]

Melbourne, Australia; 17 October 2018: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") is pleased to announce that the US Food and Drug Administration (FDA) has accepted for review Acrux's Abbreviated New Drug Application (ANDA) for its generic product based on Perrigo's Testosterone Topical Solution, 30mg/1.5mL.

Key Highlights

- Acrux has submitted an ANDA application to the FDA for its generic version of a testosterone topical solution, which has now been accepted for review
- The addressable market for the product is US$139m per annum[1]
- The product is used in males to treat conditions associated with a deficiency or absence of endogenous testosterone
- The announcement marks Acrux's second product currently under review by the FDA out of its portfolio of 13 generic topical products, following the Company's Paragraph IV ANDA for Julia® (efinaconazole) topical solution, 10%, which was accepted for review by the FDA in August 2018

Acrux CEO and Managing Director, Michael Kotsanis said:

"We are excited to announce that a second product in our generic topical pipeline is now being reviewed by the FDA for approval. This submission is another example of the exceptional work conducted by our R&D and product development teams in developing generic products that significantly lower the cost of healthcare for consumers. Acrux is now focused on continuing the progression of its strong pipeline of generic topical products."

FDA accepts for review Acrux's submission for its generic testosterone topical solution

In August 2018, Acrux submitted an ANDA to seek approval from the FDA to market a generic product equivalent to Perrigo's Testosterone Topical Solution, 30mg/1.5mL. The FDA has notified Acrux that the submission is sufficiently complete to be accepted for review.

Once approved by the FDA, Acrux will be able to commence marketing and sales of the testosterone topical solution in the United States.

[1] Twelve months sales to end March 2018 based on IQVIA (Quintiles and IMS Health) sales data

Testosterone solution 30mg/1.5mL is indicated for topical replacement therapy in males who have low or no endogenous testosterone and is applied via an axilla (armpit) applicator. Testosterone deficiency is a clinical condition in which the testicles, hypothalamus or pituitary gland is affected by disease or damage that results in decreased testosterone production.

US$139 million annual market size

The total addressable market for the product and other generics is US$139 million. There are currently no branded products on the market. As at the date of this announcement, there are 4 generic products occupying 100% of the market.

Outlook & Next Steps

Following the submission and during the FDA review process, Acrux will be focusing on forming the optimal licensing and distribution agreements to commence marketing and sales of the testosterone solution.

Acrux is fully committed to continuing the progression of the strong pipeline of topical products in its current portfolio and will continue to keep the market updated accordingly.

For more information, please contact:

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About Acrux

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising topical pharmaceuticals. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and commercialised through licensees a number of topically applied pharmaceutical products in the US and Europe. Acrux is developing of a range of generic products for the US market by leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring affordable 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