



28 July 2021

Acrux receives FDA approval for its generic version of EMLA® (Lidocaine 2.5% and Prilocaine 2.5%) Cream

Melbourne, Australia; 28 July 2021: Acrux Limited (ASX:ACR) ('Acrux' or the 'Company') is pleased to announce that the US Food and Drug Administration ('FDA') has approved its generic version of EMLA® (Lidocaine 2.5% and Prilocaine 2.5%) Cream.

In June 2019, Acrux submitted an ANDA to seek approval from the FDA to market its generic version of EMLA® (Lidocaine 2.5% and Prilocaine 2.5%) Cream. The FDA has notified Acrux that the submission has now been approved and that Acrux can manufacture and market the generic drug.

The product is indicated as a topical anaesthetic for use on normal intact skin for local analgesia, genital mucous membranes for superficial minor surgery and as a pre-treatment for infiltration anaesthesia. In the United States, sales generated by the product with which Acrux's generic will compete exceeded USD\$21 million in the 12 months to the end of September 2020, based on IQVIA data.

Acrux CEO and Managing Director, Michael Kotsanis said:

"We are pleased to receive FDA approval for our third generic product. It is a testament to the hard work and dedication of the product development and regulatory team. We look forward to announcing launch of the product in due course."

Authorised by the Board of Acrux Limited.

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