ASX/Media Release

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Acrux's third generic dossier accepted by FDA for review

Melbourne, Australia; 19 August 2019: 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 version of EMLA® (Lidocaine 2.5% and Prilocaine 2.5%) Cream.

Key Highlights

- Acrux has submitted an ANDA application to the FDA for Lidocaine 2.5% and Prilocaine 2.5% cream, which has now been accepted for review
- Annual sales for the product were US$35m as measured by IQVIA [1]
- The product is used as a topical anaesthetic
- The announcement marks Acrux's third product accepted for review by the FDA

Acrux CEO and Managing Director, Michael Kotsanis said:

"We are excited to announce that a third product in our generic topical pipeline has now been accepted for review by the FDA. This submission is a continuation of the exceptional work conducted by our R&D and product development teams in developing generic products in attractive markets that improve outcomes for consumers. Acrux remains focused on continuing the development of its strong generic topical pipeline."

FDA accepts for review Acrux's submission for its generic topical anaesthetic

In June 2019, Acrux submitted an ANDA to seek approval from the FDA to market its generic version of EMLA Cream®, Lidocaine 2.5% and Prilocaine 2.5%. 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 product in the United States.

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.

US$35 million annual market size

The total addressable market for the product including existing generics is US$35 million. There are 4 approved ANDA's for generic products as at August 2019.

[1] IQVIA March 2019 MAT. Annual product sales for previous twelve months is the addressable market.

Outlook & Next Steps

Acrux expects to have an additional 4 ANDAs accepted for review by the FDA during calendar year 2020. This is in addition to the 3 ANDA submissions and subsequent FDA acceptances for review that have been announced to date.

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

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