



7 June 2023

Acrux receives FDA approval for its generic version of Aczone® Gel, 5% (Dapsone Gel 5%)

Melbourne, Australia; 7 June 2023: Acrux Limited (ASX:ACR) ('Acrux' or the 'Company') is pleased to announce that the US Food and Drug Administration ('FDA') has approved the Company's fourth ANDA, a generic version of Aczone® Gel, 5% (Dapsone Gel, 5%).

Key Highlights:

- Acrux has received approval for its ANDA application to the FDA for Dapsone Gel, 5%
- Annual addressable market sales for the product exceeds US\$17.5 million as measured by IQVIA¹
- The announcement marks Acrux's fourth ANDA to be approved by the FDA.

In August 2021, Acrux submitted an ANDA to the FDA seeking approval to market its generic version of Aczone® Gel, 5% (Dapsone Gel, 5%). The FDA has now notified Acrux that the submission has been approved which means Acrux can manufacture and market this generic drug in the United States. A commercial partner is in place to market this product.

The product is indicated as a topical treatment of acne vulgaris in patients aged 12 years and older. In the United States, sales generated by the product with which Acrux's generic will compete exceeded USD\$17.5 million based on IQVIA data¹.

Acrux CEO and Managing Director, Michael Kotsanis said:

"We are pleased to receive FDA approval for another ANDA product which has been developed in house by the Acrux R&D team. The Dapsone Gel 5% product included bioequivalence data demonstrated through in vitro techniques, including in-vitro permeation testing (IVPT). This is the first of a number of products which Acrux has submitted to the FDA for approval that includes IVPT data."

Authorised by the Chair of Acrux Limited.

¹ IQVIA April 2023. Annual product sales for previous twelve months is the addressable market.



For more information, please contact

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About Acrux

Acrux is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products. Drawing on 25 years of experience, Acrux has successfully marketed through licensees a number of products worldwide with emphasis on the United States. Acrux is formulating and developing a range of topical generic products by leveraging its highly skilled workforce, on-site laboratories, GMP manufacturing suite, technical, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss commercial partnering and product development opportunities.

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