



Acrux receives FDA approval for its generic version of Aczone[®] Gel, 7.5%

Melbourne, Australia; 27 August 2024: 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 fifth ANDA, a generic version of Aczone[®] Gel, 7.5% (Dapsone Gel, 7.5%).

Key Highlights:

- Dapsone Gel, 7.5%, is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older
- Annual addressable market sales for the product exceeds US\$37.4 million¹
- The announcement marks Acrux's fifth topical ANDA to be approved by the FDA

The ANDA is a generic version of Aczone[®] Gel, 7.5% (Dapsone Gel, 7.5%) which is a topical treatment for acne vulgaris in patients 9 years of age and older. The FDA has notified Acrux that the submission has been approved which means Acrux can manufacture and market this generic drug in the United States.

In the United States, sales generated by the branded product and its generic competitors (with which Acrux's generic will compete) exceeded USD\$37.4 million based on IQVIA data¹.

Acrux CEO and Managing Director, Michael Kotsanis said:

"We are excited to receive FDA approval for another ANDA product which has been developed in house by the Acrux R&D team. The Dapsone Gel, 7.5% product is a complex product as defined by the FDA and the Acrux development included bioequivalence data demonstrated through in vitro techniques. This approval again demonstrates the capability of the Acrux team to execute the Company's strategy to develop our pipeline of topical products."

Authorised by the Chair of Acrux Limited.

¹ IQVIA June 2024. Annual product sales for previous twelve months is the addressable market.



For more information, please contact

Michael Kotsanis
Acrux Limited
CEO & Managing Director
P: + 61 3 8379 0100
E: michael.kotsanis@acrux.com.au

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