ASX Release

Acrux's generic dossier for Nitroglycerin Ointment 0.4% accepted by FDA for review

Melbourne, Australia; 4 July 2023: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") is pleased to announce that the United States Food and Drug Administration (FDA) has accepted Acrux's application for a generic version (Abbreviated New Drug Application or 'ANDA') of Nitroglycerin Ointment, 0.4% for review. Nitroglycerin Ointment, 0.4% is used to treat moderate to severe pain associated with chronic anal fissure.

Key Highlights:

- Acrux has submitted an ANDA application to the FDA for Nitroglycerin Ointment, 0.4%, which has now been accepted for review
- Annual addressable market sales for Nitroglycerin Ointment, 0.4% is US$19.9 million, as measured by IQVIA[1]
- Nitroglycerin Ointment, 0.4% is used to treat moderate to severe pain associated with chronic anal fissure
- The announcement marks Acrux's seventh ANDA to be accepted for review by the FDA.

Acrux CEO and Managing Director, Michael Kotsanis said:

"We are extremely pleased to advance another product from our pipeline to FDA regulatory review. Our key focus is on the continuing evolution of Acrux into a company with a diversified on-market portfolio and a well-planned pipeline of commercially valued products. Today's advancement of Nitroglycerin Ointment, 0.4% through to the regulatory submission stage is a great example of our strategy in action."

FDA accepts for review Acrux's submission

Acrux has submitted an ANDA to seek approval from the FDA to market a generic version of Nitroglycerin Ointment, 0.4%. The FDA has notified Acrux that the application is sufficiently complete to be accepted for their review. The reference listed drug is Rectiv® Ointment, 0.4% which is marketed by AbbVie Inc. in the United States.

While the FDA administers the review process, the time to ultimate approval is influenced by the number and nature of questions that may arise as the FDA progresses its review. Once the FDA grants approval, Acrux can finalise preparations with its already contracted commercial partner to commence marketing and sales of the product in the United States.

US$19.9 million addressable market

The total addressable market for the product is close to US$19.9 million. There are no approved or marketed ANDA products at present and a contracted commercial partner is in place to launch the product once FDA approval has been received.

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

The Acrux product portfolio

The Company's objective is to commercialise a pipeline of topically applied pharmaceutical products including the following products which have received FDA approval in the United States:

- Lidocaine, 2.5% and Prilocaine, 2.5% Cream, a topical anaesthetic marketed by Padagis
- Dapsone Gel, 5%, a treatment for acne vulgaris was approved in June 2023 and launch plans are progressing with our commercial partner and manufacturer
- Estradiol Spray, used to treat symptoms associated with menopause and is marketed as Evamist® by Padagis
- Testosterone Topical Solution, used to treat conditions in males which are caused by a lack of testosterone and is marketed by Dash Pharmaceuticals.

Additionally, the FDA has accepted and is currently reviewing the following products:

- Nitroglycerin Ointment 0.4%, as announced today and is a treatment for moderate to severe pain caused by chronic anal fissure
- Acyclovir Cream, 5%, a treatment for cold sores
- Dapsone Gel, 7.5%, a treatment for acne vulgaris.

Beyond that, Acrux is advancing a pipeline of products which are in varying stages of development, both at Acrux and with our contracted manufacturing partners.

The Company's main priority is on later stage projects that will reach commercialisation in the nearer term, while continuing development progress on earlier-stage products to ensure the breadth of the product pipeline.

Overall, Acrux now has 16 products in its portfolio at various stages of development and commercialisation.

Approved for release by the Acrux Board of Directors.

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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