22 June 2021

Acrux receives approval from the FDA for its generic version of Julia®

Melbourne, Australia; 22 June 2021: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") is pleased to announce that the US Food and Drug Administration (FDA) has granted approval of the Company's generic version of Julia® (efinaconazole) topical solution, 10%.

Key Points

- FDA's approval of the application represents an important milestone for Acrux, being its second approval this year of an Abbreviated New Drug Application (ANDA).
- Julia® US sales exceed $217 million per year.[1]
- Julia® is an antifungal drug indicated for the topical treatment of infections of the nail.

FDA grants approval for a generic version of Julia® developed by Acrux

In June 2018, Acrux submitted an ANDA with a Paragraph IV patent certification to seek approval from the FDA to market a generic version of Julia® topical solution, 10%, before the expiration of the Julia® listed patents in the Orange Book [2, 3]

The FDA notified Acrux in August 2018 that the ANDA submission was sufficiently complete to be accepted for review. The Company's ANDA contained the required data to demonstrate to the FDA that Acrux's generic product is bioequivalent to Julia®.

Acrux has now received approval from the FDA for its generic version of Julia® topical solution, 10%. Acrux announced settlement of the Paragraph IV patent litigation on 3 April 2019. Terms of the settlement, which include the launch date for the product, remain confidential. Following the receipt of approval from the FDA, Acrux will progress licensing negotiations with a commercial licensee to commercialise the product in accordance with the terms of the Settlement Agreement. When launched, Acrux's product will provide a lower cost alternative to Julia® for patients in the United States.

Julia® is a trademark of Bausch Health and Valeant Pharmaceuticals International, Inc.

[1] Twelve months sales to end September 2020 based on IQVIA sales data.

[2] The publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.

[3] https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms

Authorised by the Board of Acrux Limited.

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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