2 August 2018

Acrux submits first-to-file application for generic version of Julia® making it eligible for 180 days of generic exclusivity

Melbourne, Australia; 2 August 2018: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") is pleased to announce that the US Food and Drug Administration (FDA) has accepted for review the Paragraph IV Abbreviated New Drug Application (ANDA) dossier submitted by Acrux for its generic version of Julia® (efinaconazole) topical solution, 10%. The FDA has confirmed the submission date for Acrux's Efinaconazole Topical Solution 10% ANDA, which corresponds to the first date on which an ANDA could be lawfully submitted.

Key highlights

- Acrux has submitted an ANDA to the FDA for a generic version of Julia® and this has been accepted for review
- FDA confirms Acrux's submission date for its ANDA corresponds to the first date on which an ANDA with a Paragraph IV Certification could be submitted, making Acrux eligible for 180 days of generic market exclusivity on final approval
- Julia® US sales exceed $280 million per year[1]
- Julia® is an antifungal drug indicated for the topical treatment of infections of the nail
- FDA's acceptance of the application represents a key milestone for Acrux, being the first of 13 generic compounds currently in the Company's pipeline to reach this stage of development

Acrux CEO and Managing Director, Michael Kotsanis said:
"We are pleased that the first product in our current pipeline of 13 generic topical products is now being reviewed by the FDA for approval. This first-to-file Paragraph IV ANDA is the first example of our investment in our topical generic strategy and is the result of the great work by our R&D team. We look forward to updating the market on the outcomes of this application, and continued progress across our topical generic product portfolio."

FDA accepts for review Acrux's Paragraph IV ANDA for its generic version of Julia®

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

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

[1] Twelve months sales to end March 2018 based on IQVIA (Quintiles and IMS Health) 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.

The FDA has notified Acrux that the ANDA submission is sufficiently complete to be accepted for review. The Company's ANDA contains the required data that allows Acrux to demonstrate to the FDA that its generic product is bioequivalent to Jublia®.

Once approved by the FDA, and subject to the litigation process typical for first generic products, Acrux will be able to commence marketing and sales of Efinaconazole Topical Solution 10%, providing a lower cost alternative to Jublia® for patients in the United States.

About Paragraph IV ANDA and first-to-file status

Based on available information, Acrux believes it is one of the first companies to have submitted an ANDA containing a Paragraph IV Certification for this product and expects to be eligible for 180 days of generic marketing exclusivity upon final FDA approval.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act"), a company can seek FDA approval to market a generic drug prior to patent expiry, by providing data demonstrating bioequivalence to the Reference Listed Drug. To seek this approval, a generic applicant must provide in its submission a certification in relation to the patents purportedly protecting the original Reference Listed Drug that are listed in the Orange Book. In this case, Acrux has made a "Paragraph IV Certification" against each of the Orange Book listed Jublia® patents. A Paragraph IV Certification alleges invalidity, unenforceability and/or non-infringement of a patent listed in the Orange Book.

A 180-day period of exclusivity is granted on final approval to the applicant that is first-to-file a substantially complete ANDA containing a Paragraph IV Certification to a listed patent, compared to other ANDA applicants. If only one such ANDA is filed on the first day, there is only one first applicant. If two or more such ANDAs are filed on the first day, the ANDA applicants share first applicant status.

Following notification from a company filing an ANDA with a Paragraph IV Certification, the patent owner has 45 days to file a patent litigation suit asserting patents listed in the Orange Book in a United States District Court in order to initiate the litigation process under the Hatch-Waxman Act.

US market for Jublia® exceeds US$280 million annually

Jublia® is an FDA approved product and is indicated for the topical treatment of onychomycosis, also known as tinea unguium. Onychomycosis is a fungal infection of the nail that can result in thickening and yellowing of the nail and can result in separation from the nail bed.

The common fungal infection occurs in 10% of the general population, 20% of persons older than 60 years, and 50% of those older than 70 years[3].

Annual US sales for Jublia® for the 12 months ended March 2018 were US$283 million, based on IQVIA sales data.

[3] Westerberg DP, Voyack MJ. Onychomycosis: current trends in diagnosis and treatment. American Family Physician. 2013, 88 (11): 762–70.

One of the Julia® patents already ruled invalid by US Patent Trial and Appeal Board (PTAB)

Acrux previously announced *(refer to ASX announcement dated 3 November 2016)* that it had filed an *inter partes* review (IPR) for US Patent No. 7,214,506 (the '506 patent) which is one of the Julia® Orange Book listed patents. In a ruling announced recently, the US PTAB ruled in favour of Acrux, holding all claims of the '506 patent invalid.

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