



GEDEON RICHTER



RICHTER AND ACRUX ANNOUNCE EUROPEAN APPROVALS AND MILESTONE PAYMENTS FOR LENZETTO®

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BUDAPEST and MELBOURNE – Gedeon Richter Plc. (“Richter”) and Acrux (ASX: ACR) today announced that Lenzetto® has received multiple marketing approvals in European territories, triggering milestone payments totalling US\$ 2 million. Lenzetto® is Acrux’s estradiol spray for treating menopause symptoms that has been licensed exclusively in Europe to Richter.

These approvals of Lenzetto® were granted after the European decentralised procedure (DCP) was completed with the first country approval triggering a milestone payment of US\$ 1 million and the second and third approvals triggering milestone payments of US\$ 0.5 million each. Initial launches are planned for the first half of 2016, following pricing and reimbursement approvals.

“The approvals for Lenzetto® are good news for both patients and physicians in Europe,” said Michael Kotsanis, CEO and Managing Director of Acrux. “We are confident that Lenzetto® will provide doctors with an innovative additional therapy option to successfully treat their patients who are suffering from menopausal symptoms.”

Acrux’s estradiol product is branded Lenzetto® in Europe and Evamist® in the United States. Evamist® has been on sale in the US since 2009.

Based on 2014 IMS data, the European (including Russia) estrogen only HRT market, had annual sales of over EUR 85 million.

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About Gedeon Richter Plc

Gedeon Richter Plc. (www.richter.hu), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe. Richter's consolidated sales were approximately EUR 1.1 billion (US\$ 1.5 billion), while its market capitalization amounted to EUR 2.1 billion (US\$ 2.5 billion) in 2014. The product portfolio of Richter covers almost all important therapeutic areas, including gynaecology, central nervous system, and cardiovascular areas. Having the largest R&D unit in Central Eastern Europe, Richter's original research activity focuses on CNS disorders. With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the female healthcare field worldwide. Richter is also active in biosimilar product development.

About Acrux Ltd

- Acrux is an Australian drug delivery company, developing and commercialising a range of patient-preferred, patented pharmaceutical products for global markets, using its innovative technology to administer drugs through the skin.
- The Acrux technology, used in marketed products including AXIRON[®], Evamist[®] and Recuvyra[™], is based on a fast-drying, small volume, accurately dosed solution, containing penetration enhancers, that when applied topically, deposit drug through the skin for long acting delivery.
- Acrux has three products marketed by licensees in the USA, three products approved in Europe, and further products at earlier stages of development.

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

About Lenzetto[®]

Acrux's estradiol product is different to other transdermal products. The spray is applied clear, generally dries in less than two minutes and has a low incidence of reported skin irritation.

Acrux's estradiol transdermal spray is not formulated as a membrane controlled reservoir or solid matrix system requiring a backing, adhesive and release liner. Accordingly, the product has several potential advantages over currently approved transdermal estrogen products.

Clinical studies have shown that estradiol delivered in the Ellavie formulation is absorbed through the skin and provides efficacious serum concentrations for the treatment of vasomotor symptoms in postmenopausal women. The fast-drying spray delivers a low dose of estradiol, resulting in therapeutic blood levels similar to the exposure range for other approved estrogen products.