ASX ANNOUNCEMENT

13 July 2022

Zenivol® achieves major milestone with formal regulatory approval received in Germany

ZENIVOL® REACHES SIGNIFICANT MILESTONE BY RECEIVING FORMAL FEDERAL REGULATORY AUTHORITY (BFARM) APPROVAL IN GERMANY

Key Highlights

- Zenivol® receives formal approval from German regulatory authority BfArM, for commercialisation by Adjupharm GmbH
- Formal approval of Zenivol® is a major milestone in Zelira's expansion into Germany, one of the world's largest markets for cannabinoid-based medicines and Europe's largest market
- Advances the Company's global commercialisation strategy to grow its Pharmaceutical (Rx) portfolio
- Expands the availability of Zenivol® beyond Australia for the first time
- Reinforces the pharmaceutical quality of Zelira's Australian production capabilities, including the safety and efficacy of Zelira's clinically validated cannabinoid-based medicines

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the research, development and commercialisation of clinically validated cannabinoid medicines is pleased to announce that Zenivol® has received formal approval from the German regulatory authority BfArM (The Federal Institute for Drugs and Medical Devices Bundesinstitut für Arzneimittel und Medizinprodukte) via its German commercialisation partner Adjupharm GmbH (Adjupharm).

This approval is a necessary and major milestone for Zelira to enter Germany, one of the world's largest markets for cannabinoid-based medicines and Europe's largest market, via its 5-year exclusive distribution agreement with Adjupharm (announced in September 2021).

This approval will expand the availability of Zenivol®, Zelira's clinically validated cannabinoid-based insomnia medication, beyond Australia for the first time.

German regulatory approval highlights Zelira's expertise in quality and pharmaceutical production and supports the Company's strategy of further validating the safety and efficacy of Zenivol® and Zelira's other clinically, real world data backed cannabinoid-based medicines.

Zelira Therapeutics Managing Director, Dr Oludare Odumosu commented:

"The formal approval of Zenivol® by BfArM in Germany marks a major milestone for our business. Germany is one of the largest global markets for cannabinoid-based medicines, and also one of the highest quality global regulatory markets for pharmaceuticals. We look forward to working with our Partner, Adjupharm in launching Zenivol® in Germany and supporting patients and physicians in treating chronic insomnia in a safe and effective manner. With formal regulatory approval for Zenivol® now received in Germany, we continue to progress activities to license Zenivol® into other global markets." ."

This announcement has been approved and authorised for release by the board of Zelira Therapeutics Limited.

For further information please contact

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About Zelira www.zeliratx.com

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) is a leading global biopharmaceutical company in the research, development and commercialisation of clinically validated cannabinoid medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to access the world's largest and fastest growing markets. The Company is focused on developing and clinically validating branded cannabinoid-based medicines for the treatment of a variety of medical conditions in its Rx business, including insomnia, autism and chronic non-cancer pain.

The Company has two proprietary formulations under the HOPE® brand that are generating revenues in Australia, Pennsylvania, Louisiana and Washington D.C. with other states in the US expected to follow. Zelira is also generating revenue in Australia from its proprietary and patented Zenivol® - a leading cannabinoid-based medicine for treatment of chronic insomnia. Zenivol® has successfully completed the first Phase 1b/2a clinical trial for chronic insomnia where it was found to be a safe and effective treatment. This clinical trial is published in the prestigious journal 'Sleep'. In 2020, Zelira partnered with SprinJene®Natural to develop and commercialise natural and organic oral care products under the SprinjeneCBD brand, as part of Zelira's OTC business. The SprinjeneCBD toothpaste product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids and based on the proprietary and patented technology of Blackseed oil and Zinc.

The Company conducts its work in partnership with world-leading researchers and organizations which since inception includes Curtin University in Perth, Western Australia; the Telethon Kids Institute in Perth; the University of Western Australia, in Perth; St. Vincent's Hospital in Melbourne, Australia; and the Children's Hospital of Philadelphia (CHOP) in the United States.

For further information, please visit: zeliratx.com