ASX Release

12 July 2021

Zelira US Observational Clinical Pain Trial Receives IRB Approval

- **Institutional Review Board (IRB) approval received, allowing Zelira's pain observational trial in USA to proceed**
- **Study will be a head-to-head study against a major Big Pharmaceutical company's multi-billion-dollar revenue drug, using Zelira's proprietary, patent protected product**
- **Preliminary results expected in 1H of 2022**
- **Zelira continues to lead the world in creating and validating proprietary products such as Zenivol® with a focus on taking these drugs through regulatory registration.**

Zelira Therapeutics Ltd (**ASX:ZLD, OTCQB:ZLDAF**), a global leader in the development of clinically validated cannabinoid-based medicines, is pleased to announce that it has obtained IRB approval for its 12 week Observational Clinical Study to evaluate the efficacy, safety and tolerability of its proprietary, patent protected product against a multi-billion dollar Big Pharmaceutical company drug.

Zelira has successfully navigated a unique regulatory path for this trial and looks forward to the results of the study, which is anticipated to be available in the first half of 2022. Zelira continues to lead the world in creating and validating proprietary products such as Zenivol®, with a focus on taking these drugs through regulatory registration.

Zelira Therapeutics Chairman, Osagie Imasogie commented: *"We are very pleased with receiving our IRB approval. We are even more pleased that we can conduct this innovative trial that we hope will provide additional safe and effective options for physicians and patients in the treatment of pain caused by neuropathy."*

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

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Zelira Therapeutics Ltd (**ASX:ZLD, OTCQB:ZLDAF**) is a leading global biopharmaceutical company manufacturing and marketing cannabinoid-based medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to access to 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 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 including 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.