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Clinical trial results of Zelira's Zenivol® published in the prestigious peer-reviewed journal *SLEEP*®

- The University of Western Australia research team has published the results from its double-blind, placebo controlled, cross-over trial of Zelira's ZTL-101 (on market as Zenivol®) in chronic insomnia patients in the peer-reviewed journal *SLEEP*®
- When first announced, in February 2020, the results of this trial were the world's first clinically validated cannabis formulation for treating insomnia
- *SLEEP*®, the official publication of the Sleep Research Society, is the benchmark international journal for all sleep-related conditions with a mission to publish innovative, high-impact research findings across the basic, translational, and clinical research spectrum
- Publication in the prestigious *SLEEP*® journal provides the foremost evidence- based, peer-reviewed clinical trial data for doctors who treat patients with chronic insomnia
- 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 the University of Western Australia's investigational team that undertook the double-blind, placebo controlled, cross-over trial of Zelira's ZTL-101 (on market as Zenivol®) in chronic insomnia patients has had the results of its trial published in the peer-reviewed journal *SLEEP*®, available [here](#).

SLEEP® is the benchmark international journal for all sleep-related conditions with a mission to publish innovative, high-impact research findings across the basic, translational, and clinical research spectrum. It is the official publication of the Sleep Research Society.

The trial was undertaken at the world-class University of Western Australia Centre for Sleep Science and was led by principal investigator Professor Peter Eastwood with Dr Jennifer Walsh as the corresponding author. Zelira first announced the positive Phase 1b/2a results on 19 February 2020 and provided additional detail on the primary and secondary endpoints achieved on 7 April 2020.

As outlined in the manuscript, chronic insomnia is present in between 6-15% of the population and is associated with adverse health outcomes. Current pharmacological treatment options are often unsatisfactory with significant side effects. The published results demonstrated that following 2-weeks of using Zelira's ZTL-101, patients saw a significant decrease in insomnia symptoms relative to placebo.

Zelira's proprietary Zenivol® formulation was launched in Australia in September 2020 and is available to prescribers and patients through the Therapeutic Goods Administrations (TGA) Special Access and Authorised Prescriber Schemes

Zelira Therapeutics Managing Director, Dr Oludare Odumosu commented: *"Physicians and patients often ask for published peer-reviewed data from a double-blind, placebo-controlled, cross-over study. With this publication in the prestigious and high impact journal of SLEEP® of the results from the University of Western Australia's trial, we can confidently say "here you have the first scientific peer-reviewed publication for a cannabinoid medicine to treat insomnia".*

"Now, prescribers will have a higher level of confidence in using Zelira's Zenivol® to treat their patients battling chronic insomnia. Zelira is committed to taking Zenivol® through registration approval as the worlds' first fully validated and approved cannabinoid treatment for chronic insomnia."

Lead Author, Dr Jennifer Walsh, said: *"This is an exciting publication as it is the first report of a scientifically rigorous study of any cannabinoid formulation for treating insomnia. The results demonstrate significant improvements in a number of important insomnia metrics which is encouraging preliminary evidence that ZTL-101, Zelira's Zenivol®, has potential to treat this highly prevalent condition."*

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

- ENDS -

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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 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, that will be launched by Zelira's Oral Care OTC business.

Zelira 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.

About SLEEP® (<https://academic.oup.com/sleep>)

SLEEP® is a peer-reviewed, international journal of sleep and circadian science, and is the official publication of the Sleep Research Society (SRS).

SLEEP® is the benchmark international journal for sleep and circadian science. The mission of SLEEP® is to publish innovative, high-impact research findings in sleep and circadian science across the basic, translational, and clinical research spectrum. SLEEP® seeks to advance our understanding of sleep and circadian rhythms, as well as their contributions to health and disease.