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## Clinical trial results of Zelira's Phase 1 dose escalation study in chronic pain patients on long-term opioid treatment published in the peer-reviewed journal *Pain And Therapy*

CLINICAL TRIAL RESULTS OF ZELIRA'S PHASE 1 PUBLISHED IN THE PEER-REVIEWED JOURNAL PAIN AND THERAPY

### Key Highlights

-  The St Vincent's Hospital Melbourne (SVHM) research team has published the results from its Phase 1 open label study that examined the pharmacokinetics, safety and tolerability of escalating doses of a medicinal cannabis product in patients with chronic non-cancer pain (CNCP)
-  *Pain And Therapy* is an international, peer-reviewed publication dedicated to the publication of high-quality clinical research around the discovery, development and use of pain therapies and pain-related devices
-  Supports Zelira's position as a global leader in the development of cannabinoid-based therapies



Philadelphia, PA - December 23, 2021 - 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 St Vincent's Hospital Melbourne (SVHM) Department of Addiction Medicine research team that undertook the open label dose escalation trial in chronic non-cancer pain patients has had the results of its trial published in the peer-reviewed journal *Pain And Therapy*, available [here](#).

*Pain And Therapy* is an international, peer-reviewed journal dedicated to the publication of high-quality clinical research around the discovery, development and use of pain therapies and pain-related devices. The journal is read by a global audience and assists in the dissemination of all scientifically and ethically sound research.

The trial, which results were originally announced on 14 July 2020, was led by the coordinating investigator Associate Professor Yvonne Bonomo at the SVHM Department of Addiction Medicine in conjunction with Emyria (ASX: EMD). As outlined in the manuscript, nine people with chronic non-cancer pain and an oral morphine equivalent daily dose (OMEDD) of  $\geq 60\text{mg}$  were recruited. The study provides important pharmacokinetic and safety data in a clinical population with multiple physical comorbidities and polypharmacy who are often excluded from clinical trials. Observed improvements in pain interference scores, mood, and some sleep parameters suggest areas for further investigation under randomized controlled clinical trial conditions.

Publication of the trial in an international peer-reviewed journal is testament to Zelira's commitment to work with world-class researchers undertaking research that is critical to the continued maturation of the medicinal cannabis industry as a pharmaceutical grade treatment.







**Zelira Therapeutics Managing Director, Dr. Oludare Odumosu commented:**

“The publication of these trial results is further testament of Zelira’s world class pharmaceutical manufacturing and commitment to producing the highest quality, evidence-based cannabinoid medicines.

In addition, Zelira has leveraged the knowledge gained from this work to support the development of the proprietary formulation which we have licenced to Levin Health and to inform the design of other chronic non-cancer pain trials.”



**Lead Investigator and author, Associate Professor Yvonne Bonomo said:**

“We were very pleased to work with Zelira on this project which exemplifies our joint commitment to ensuring quality and safety in the implementation of medicinal cannabis use in the community.”



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





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#### About Zelira [www.zeliratx.com](http://www.zeliratx.com)



Zelira Therapeutics Ltd 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 as well as offering over the counter (OTC) products.

The Company has two proprietary formulations under the HOPE™ brand that are generating revenues in Australia, Louisiana and Washington D.C. with other States in the US expected to follow.

Zelira is also generating revenue in Australia and Germany from its proprietary and patented Zenivol® - a leading cannabinoid-based medicine for treatment of chronic insomnia. Zenivol® has successfully completed the world's first cannabinoid-based efficacy trial for chronic insomnia where it was found to be a safe and effective treatment. This clinical trial was published in the prestigious peer-reviewed 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 has worked in partnership with world-leading researchers and organisations, which since inception include 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.

