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ZELIRA SUCCESSFULLY SUPPORTS LEVIN HEALTH'S RECEIPT OF ETHICS APPROVAL

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APPROVAL FOR PHASE 2A CLINICAL TRIAL FOR CHRONIC PAIN

Key Highlights

-  Zelira Therapeutics has successfully project managed ethics approval for a Phase 2a clinical trial to evaluate the efficacy of its licensed patented cannabinoid formulation, ZTL-106, in treating patients with chronic pain.
-  Levin Health licensed ZTL-106 from Zelira and are the sponsors of the trial being undertaken at La Trobe University's Sport and Exercise Medicine Research Centre (Melbourne, Australia).
-  This outcome further cements Zelira's ability to design and have approved clinical trials with medicinal cannabis products.



Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the development of clinically validated cannabis medicines is pleased to announce that as part of its Licensing and Project Management Agreement with Levin Health (Levin), announced 3 June 2021, the Phase 2a clinical trial to evaluate the efficacy of Zelira’s patented cannabinoid formulation, ZTL-106, in treating patients with chronic pain has received ethics approval.

In June 2021, Zelira announced it had licensed ZTL-106 to Levin for the purpose of undertaking a clinical trial to test the efficacy of the formulation in treating sports-related chronic pain experienced by retired professional and amateur athletes. Under the terms of the Licensing and Project Management Agreement, Levin will provide the funding for the trial and Zelira will be contracted to project manage the trial.

Undertaken in collaboration with La Trobe University’s Sport and Exercise Medicine Research Centre (Melbourne, Australia), the randomised, double blind, placebo controlled clinical trial will investigate the use of ZTL-106 as an effective medicinal cannabis drug in treating people with chronic pain specifically following musculoskeletal injury. World-renown sports medicine expert Professor Peter Brukner is the Principal Investigator for the trial.

With the approval now formally received from the Bellberry Human Research Ethics Committee (HREC), the trial is expected to commence in April 2022, and will aim to enroll 114 patients.



Zelira Therapeutics Managing Director, Dr Oludare Odumosu commented:

“Zelira is excited to have partnered with Levin Health in this innovative drug development project. We are thrilled that our world class formulation and expertise in fast tracking drug developments has been born out with the Bellberry ethics approval for this phase 2 clinical trial. We look forward to continuing our partnership with Levin Health to validate a proprietary product that will help treat chronic pain.”



Levin Health’s Managing Director, Mark Brayshaw commented:

“Our vision is to help solve the challenges faced by current and former athletes and help everyday people stay active and live a healthy lifestyle. As such, we work with world-leading researchers to explore and conduct evidence-based sport science related research. Receiving HREC approval for our trial is a huge step forward for Levin Health. To the best of our knowledge, this trial will be the first of its type globally in terms of evaluating the efficacy of medicinal cannabis in the treatment of chronic, non-cancer pain under strict controlled conditions. Our investment in this phase 2 clinical trial will separate Levin Health from our competitors. This is just one trial in our long-term strategy and will be a very valuable asset once completed.”

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



Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) is a leading global therapeutic medical cannabis company with access to the world's largest and fastest growing cannabis markets. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to enter global markets. The Company is focused on developing 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 and have been licensed in 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 world's first Phase 1b clinical trial for chronic insomnia where it was found to be a safe and effective treatment. 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.



About Levin Health www.levinhealth.com.au



LEVIN Health is an Australian sport science company, committed to solving some of the most challenging health issues facing sports people and the wider community, including chronic pain and concussion/mTBI.



LEVIN Health uses sport advocacy and leadership to support its evidenced based research to help find treatment options for these growing health issues.

LEVIN Health currently has a range of prescription products available under the Levin™ brand accessible through the Special Access Scheme and Authorised Prescriber pathways. All products are made in Australian GMP-certified facilities with Australian cannabis. They are committed to developing and providing the best cannabis-based medicine possible.