

3 June 2021

# ZELIRA THERAPEUTICS AND LEVIN HEALTH ENTER LICENSING AND MANAGEMENT AGREEMENT TO CONDUCT CHRONIC PAIN TREATMENT CLINICAL TRIAL ON RETIRED ATHLETES

- Zelira Therapeutics has licensed its ZTL-106 proprietary cannabinoid formulation to Levin Health for a chronic pain treatment clinical trial on retired athletes
- Levin Health will sponsor the trial and pay Zelira a management fee to design and manage the study
- Zelira will hold marketing rights for North & South America with Levin Health holding rights to all other world markets
- Levin Health and Zelira will share profit from the commercialisation of products from the formulation
- This agreement expands and complements Zelira's strategic interests in chronic pain treatments while maintaining the Company's focus on the global growth of its proprietary insomnia and HOPE™ products.

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 licensed a proprietary cannabinoid formulation to Levin Health Limited (Levin Health) 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.

Studies show that retired athletes are more likely to suffer chronic pain and associated conditions such as depression and anxiety as a result of injuries and physical exertion over long periods of time. While clinical data is currently limited, medicinal cannabis may provide a safe and effective targeted treatment option for this large cohort. The clinical trial to be conducted by Levin Health will address this.

In addition to licensing the proprietary formulation to Levin Health, Zelira and Levin Health have entered into a Project Management Agreement, whereby Levin Health will pay for the trial and engage Zelira to project manage the clinical trial to be undertaken at La Trobe University's Sport and Exercise Medicine Research Centre in Victoria, Australia.

The licensing and project management agreements between Zelira and Levin Health utilise Zelira's leading intellectual property portfolio and expertise in clinical trial design for medicinal cannabis, including chronic pain, along with Levin Health's advisory team and network of retired professional athletes. This targeted

approach provides an opportunity to build a leading international brand supported by clinical data that addresses a specific and widespread unmet global medical need.

**Zelira Therapeutics Managing Director, Dr Oludare Odumosu commented**: "Zelira is thrilled to partner with Levin Health on this innovative drug development project. This collaboration demonstrates Zelira's world class formulation and expertise in fast tracking drug development. This partnership also leverages Levin Health's mission to impact chronic pain treatment approaches. We look forward to creating and validating a proprietary product that will help treat chronic pain."

**Levin Health Chief Executive Officer, Mark Brayshaw, said**: "Levin is delighted to partner with Zelira in this world class trial investigating ZTL-106 as a potential treatment for chronic pain in athletes. Quality clinical trial data is a vital requirement to validate cannabinoids as medicine, and Zelira are doing some of the best clinical work in the sector in Australia and globally. Chronic pain is one of the major health issues facing not just athletes, but all active Australians, and we have high hopes for the trial."

# **DISCLOSURES**

- The commencement date of the Project Management Agreement is 3 June 2021, Zelira will receive a management fee to act as Project Manager.
- The contract is for the duration of the clinical trial and may be extended by mutual written consent.
- The Company cannot, at this stage, fully quantify the impact of the contract will have on the price of its securities.
- As is usual in these agreements, the Agreement is terminable mutually or when one party fails to perform by either party giving written notice.
- The Company notes that Zelira Directors Jason Peterson & Harry Karelis are shareholders and option holders in Levin Health Limited holding approximately 3.9% of total shares on issue between them. However, neither Mr Peterson nor Mr Karelis individually or together control and are not directors of Levin Health Limited. The Board of Zelira excluded Mr Peterson and Mr Karelis from any discussions related to this agreement with Levin.

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

Oludare Odumosu Managing Director USA

- ENDS -

For further information please contact:

#### Company

Dr Oludare Odumosu Managing Director & CEO +1 909 855 0675 oodumosu@zeliratx.com

## Investors

Market Eye Pty Ltd ABN 54 137 305 527 Melbourne | Sydney T: +61 3 9591 8900 F: +61 3 9591 8999

W: www.marketeye.com..au

# About Zelira Therapeutics (www.zeliratx.com)

## **Australia**

Level 3 101 St Georges Terrace Perth WA 6000 AUSTRALIA

Tel: +61 8 6558 0886 Fax: +61 8 6316 3337 E: enquiries@zeliratx.com W: www. zeliratx.com ACN 103 782 378

# **USA**

5110 Campus Drive Suite 150 Plymouth Meeting, PA 19462 UNITED STATES OF AMERICA Tel: +1 484-630-0650

Zelira Therapeutics Ltd 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 proprietry 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 (www.levinhealth.com.au)



Levin Health is a privately held, Melbourne-based Medicinal Cannabis company, established to be the World Leader in using science and natural plant extracts to solve sports most challenging health issues. The Company's mission is to allow athletes and sporty people who suffer from chronic pain to stay active using non-opioid, non-steroid treatments. Levin Health is focussed on treating sports-related chronic pain, supported by world class clinical trials, athlete care programs and patient education.