ASX
ANNOUNCEMENT

30th May 2022

Zelira Completes Enrolment for Diabetic Nerve Pain Drug Trial

DIABETIC NERVE PAIN DRUG TRIAL ENROLMENT

Key Highlights

- The IRB approved trial has been designed as a multi arm head-to-head against a major Big Pharmaceutical company's multi-billion dollar revenue drug, using Zelira's proprietary, patent protected product
- Zelira has completed enrolment for the first subject group of this trial
- Complete clinical trial results expected in the second half of 2022

PHILADELPHIA, 30 May, 2022 – Zelira Therapeutics Ltd (ASX: ZLD) (OTCQB: ZLDAF), a global leader in the research, development and commercialisation of clinically validated cannabinoid medicines, is pleased to announce the complete enrolment of the investigative drug arm of its IRB approved pain drug trial, announced 12 July 2021.

This trial will evaluate the efficacy, safety and tolerability of Zelira's proprietary, patent protected product against a multi-billion dollar Big Pharmaceutical company drug. This is a very significant milestone for the trial, designed as a multi arm head-to-head comparison of 60 subjects with 20 subjects in each arm, powered to show statistical difference. A total of 20 patients in the investigative drug arm have been completely enrolled, with clinical trial results expected by the end of this year.

Zelira has partnered with Pennsylvania Global CRO, Affinity Bio Partners to manage this clinical trial. Christina DiArcangelo, CEO of Affinity Bio Partners said:

"This is a monumental achievement. Medical cannabis patients need valid clinical studies to prove efficacy and safety with cannabinoids and other components of the cannabis plant structure. It is time for the medical cannabis industry to raise the bar to the level that Zelira has with their focus on clinical research."

Lead Principal Investigator for this clinical trial, Dr. Bryan Doner, DO, CHWS, FACHM, D&P Medical Group said:

"Medical cannabis research such as we are performing is critical not only to continue improving patient care and safety, but also to help substantiate the true potential benefits of medical cannabis and help drive regulatory reform."

Zelira Therapeutics CEO and Managing Director, Dr. Oludare Odumosu said:

"This product trial exemplifies Zelira's strategy to continue generating clinical validation for cannabinoid-based medicines. We are very pleased at the rate of recruitment for this clinical trial and look forward to what we hope will be positive results. The value proposition of Zelira has always been our 'multiple shots on goal' strategy that covers both our OTC products and our RX prescription products, that best positions our company for success, and that we continue to deliver on."

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

For further information please contact

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

Investors
Ronn Bechler
Executive Chairman, Market Eye
+61 400 009 774
ronn.bechler@marketeye.com.au

About Zelira Therapeutics

Australia
Level 3, 101 St Georges Terrace
Perth WA 6000, AUSTRALIA
+61 8 6558 0886
Fax: +61 8 6316 3337
enquiries@zeliratx.com
www.zeliratx.com
ACN 103 782 378

USA
5110 Campus Drive, Suite 150
Plymouth Meeting, PA 19462
United States Of America
+1 484-630-0650

About Zelira www.zeliratx.com

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) is a leading global biopharmaceutical company in the research, development and commercialisation of clinically validated cannabinoid medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical develop-ment 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 treat-ment 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/2a 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 which since inception includes 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 Affinity Bio Partners www.affinitybiopartners.com

Affinity Bio Partners is leading voices for safe and ethical clinical trials while working with stakeholders globally to promote a better and more efficient clinical trial process. Affinity Bio Partners maintains an unwavering dedication to bringing efficiency, safety, innovation and value to the clinical research process.