ASX
ANNOUNCEMENT

21 November 2022

Zelira Completes Enrolment for Diabetic Nerve Pain Drug Trial

IRB APPROVED HEAD-TO-HEAD TRIAL READ OUT EXPECTED Q1 2023

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 now completed enrolment of the multi arm head-to-head clinical trial
- Trial read out expected in Q1 2023

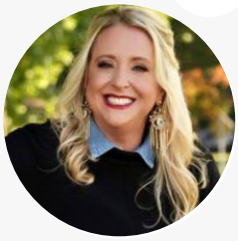
Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the research, development and commercialisation of clinically validated cannabinoid medicines, is delighted to announce the successful enrolment of the 60 patient in the clinical trial for diabetic nerve pain[1], to evaluate the efficacy, safety and tolerability of its proprietary, patent protected product against a multi-billion-dollar Big Pharmaceutical company drug.

The trial was designed and approved as an observational multi-arm, head-to-head study. The study was powered to show statistical difference with 60 subjects (20 subjects in each arm).

- Group 1: Subjects will be already taking reference drug at the prescribed dose as recommended by their doctor.
- Group 2: Subjects already taking reference drug at the prescribed dose as recommended by their doctor. Will receive investigative drug -One capsule by mouth twice daily. If no response after two weeks, Principal Investigator can increase the dosing to three times daily. If the Principal Investigator feels that a subject needs an additional dose, an additional capsule can be provided so that the subjects are dosed four times daily. Study drug will be taken by the subjects in the privacy of their own homes.
- Group 3: One capsule of Zelira's proprietary investigational drug, ZLD 007, by mouth twice daily. If no response after two weeks, Principal Investigator can increase the dosing to three times daily. If the Principal Investigator feels that a subject needs an additional dose, an additional capsule can be provided so that the subjects are dosed four times daily.

Following completion of the trial enrolment Zelira expects to provide a trial read out in Q1 2023.

Zelira Therapeutics CEO & Managing Director, Dr. Oludare Odumosu said:
"Our company is pleased with the successful completion of enrolment of this IRB approved trial, conducted in the United States and look forward to the analyses and readout of the study results. This unique, multi-arm comparative study presents multiple prospects for positive readouts on study endpoints. A positive result on one or more endpoints would be a landmark event for our company and in line with our value creation strategy of generating scientifically rigorous, clinically validated data for our patent protected, proprietary cannabinoid-based drugs . Above all, positive results will validate the real potential for creating safer and efficacious cannabinoid medicines for the treatment of diabetic nerve pain. In addition, results from this trial will also validate the safe and efficacious use of Zelira's patent protected, proprietary technology Zyraydi™, which was used to formulate our investigational drug, in humans."



Zelira partnered with Pennsylvania Global CRO, Affinity Bio Partners to manage this clinical trial. Christina DiArcangelo, CEO of Affinity Bio Partners said:
"Despite having to overcome challenges such as the COVID-19 pandemic, and educating subjects about new cannabinoid-based therapies including terpene education, Affinity Bio Partners is proud to have been able to successfully complete subject enrollment for this study alongside its partners Spectral Analytics Precision Tele-Monitoring for electronic patient reported outcomes and electronic data capture, and non-profit patient advocacy sponsor, Affinity Patient Advocacy for subject recruitment along with the clinical trial sites. I am grateful to see a dream come true for a Global Cannabinoid Biotechnology purposely targeting big pharmaceutical approved treatment. In order for cannabinoid treatments to be taken seriously, we need to ensure that there are more validated, scientific, well designed true clinical studies against traditional pharmaceutical products. It is time to provide patients with cannabinoid choices once the studies have been completed, and regulatory approvals are received"

Bryan Doner, DO, CHWS, FACHM, Lead Principal Investigator said:

"We are very excited to announce completion in enrollment for the Diabetic Neuropathy study. We believe the patient experience during this study has been tremendous, and we greatly anticipate evaluating the data collected. We are hopeful that through this and similar research, novel and alternative treatment plans for Diabetic Neuropathy can be further explored and developed."

[1] Refer ASX announcements 12 July 2021 and 21 September 2022

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 Director, Automic Group
+61 400 009 774
ronn.bechler@automicgroup.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) Zelira is a leading global biopharmaceutical company in the research, development and commercialisation of clinically validated cannabinoid-based medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development positioned to enter global markets. The Company is focused on developing and clinically validating branded cannabinoid-based medicines in its prescription [Rx] business for the treatment of a variety of medical conditions including insomnia, autism and chronic non-cancer pain as well as offering over the counter [OTC] products.

Zelira's Rx business generates revenue from two proprietary medications, HOPE® and ZENIVOL®. The Company has two proprietary formulations under the HOPE® brand that are generating revenue in Australia, Washington, D.C., Pennsylvania and Louisiana.

Zelira is also generating revenue in Australia from its proprietary and patented ZENIVOL® – the world's first clinically validated cannabinoid drug for treatment of chronic insomnia. Zelira will also be expanding commercialisation of ZENIVOL® into Germany via its German commercialisation partner Adjupharm GmbH following recent approval from German regulatory authority BfArM.

Zelira's OTC products in the oral and dermatology health care sectors are also generating revenue. Zelira, in partnership with SprinJeneCBD, launched a full line of oral care products, currently generating revenue in the US. The SprinJeneCBD toothpaste product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids, blackseed oil and zinc utilising proprietary and patented technology. Zelira also launched in 2021 the RAF FIVE™ brand, which consists of five OTC acne treatment products using a proprietary formulation incorporating cannnabidiol (CBD).

Zelira has developed Enhanced Distillate Capture and Dissolution Matrix (EDCDM) technology under the brand name Zyraydi, that solves the problem of non-uniformity and separation of cannabinoid from powder bed, opening new ways to develop pharmaceutical grade solid oral dosage forms such as capsules and tablets. Zelira will be assessing opportunities for commercialisation of this technology.

The Company conducts its work in partnership with world-leading researchers and organisations which since inception includes Curtain University in Perth, Australia; the Telethon Kids Institute in Perth, Australia; the University of Western Australia, in Perth, Australia; St Vincent's Hospital in Melbourne, Australia; and the Children's Hospital of Philadelphia (CHOP) in the United States.

For further information, please visit: **zeliratx.com**