ASX
ANNOUNCEMENT

15 September 2022

Zelira Completes two-thirds of Enrolment for Diabetic Nerve Pain Drug Trial

IRB APPROVED TRIAL COMMENCED AND DUE TO READ OUT IN Q4 2022

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 two-thirds (40 subjects) of the multi-arm head-to-head clinical trial
- Complete trial enrolment and trial read out expected in Q4 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 successful enrolment of 40 out of 60 patients in the clinical trial for diabetic nerve pain, announced 12 July 2021.

The trial was designed and approved as a multi-arm, head-to-head trial against a major Big Pharmaceutical company's multi-billion dollar revenue drug, using Zelira's proprietary, patent protected product.

The trial is powered to show statistical significance with 60 subjects (20 subjects in each arm). In May 2022, Zelira announced the complete enrolment of 20 patients in arm 1, being the investigative drug arm of the trial. An additional 20 subjects currently using the Big Pharmaceutical company drug, have been successfully enrolled. The second arm will serve as an active reference arm for the trial, with the trial designed where the third arm will evaluate the synergistic effect (combined effects) of the reference drug.

Zelira expects to complete trial enrolment and provide a trial read out in Q4 2022.

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

"We are very pleased with the pace of enrolment and now focused on completing the full patient recruitment for this trial. We appreciate the professionalism of Affinity Bio Partners in ensuring all patients satisfy screening protocols of the trial during a global pandemic. Zelira's product has the potential to be comparable to the Big Pharmaceutical reference product or show significant difference in measures of increased efficacy, safety and/or tolerability. Delivering on one or more of these endpoints would be a significant milestone for our company and further validate Zelira's ability to create meaningful cannabinoid-based drugs that are safe and efficacious in treating various conditions."

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

"This an amazing accomplishment to have enrolled two-thirds of the trial participants so quickly, especially as we continue to navigate the challenges of Covid. Data integrity is key, therefore it is very important to ensure that the proper subjects are screened and enrolled in this pivotal clinical trial."

For further information please contact

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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**