11 July 2024

Zelira Advances HOPE® Autism Drug Program with US FDA Meeting

ZELIRA ENTHUSIATIC FOLLOWING MEETING

Key Highlights

- US FDA promptly responded to Zelira's meeting request, setting a meeting date for July 10, 2024.
- Zelira received a positive and clear written response from the FDA to preliminary questions.
- Following the positive feedback and productive meeting, Zelira looks forward to receiving the official meeting notes from the FDA
- Zelira is poised to progress the HOPE® program toward Investigational New Drug (IND) submission

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the development and commercialisation of clinically validated cannabis medicines is pleased to announce a significant advancement in its HOPE® autism drug program following a successful meeting with the United States Food and Drug Administration (FDA) today. Zelira received a positive and clear written response from the FDA to preliminary questions submitted ahead of the meeting. This response provided essential clarity on all matters presented, particularly in defining the indication for treatment of irritability associated with Autism Spectrum Disorder (ASD) in patients with Phelan-McDermid Syndrome (PMS) and Smith-Magenis Syndrome (SMS).

The meeting was attended by key stakeholders, including the principals of iNGENu CRO, whose expertise significantly contributed to the productive dialogue. During the meeting, Zelira discussed the design of the IND-opening Phase 1 study in healthy volunteers. The FDA provided guidance on the study design, aiming to evaluate the safety and pharmacokinetics of the proposed doses of ZEL-HOP1, ensuring a robust framework for further clinical development. Following the positive feedback and productive meeting, Zelira is poised to progress the HOPE® program toward Investigational New Drug (IND) submission, marking a significant step forward in the development of treatments for irritability associated with ASD.

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

Dr Oludare Odumosu, Zelira Therapeutics Managing Director, expressed the Company's enthusiasm:

We are particularly pleased with the FDA's prompt and detailed response to our preliminary questions. The clarity provided by the FDA, especially regarding the indication and study design, is incredibly positive for our company and the HOPE® SPV program. This meeting represents a crucial step forward in our mission to develop effective treatments for autism-related irritability.

The meeting, which included detailed discussions on various aspects of the HOPE® program, provides the FDA's guidance to Zelria for the proposed pathway forward. The positive outcome of the FDA meeting signifies a major milestone in the Company's journey to improve the quality of life for individuals affected by autism. Zelira now looks forward to receiving the official meeting notes from the FDA, which will guide the next steps in the IND submission process.

The expertise and collaborative spirit of our CRO team, iNGENu, along with the invaluable guidance from the FDA, reinforce our commitment to bringing innovative and effective treatments to patients with ASD. We are eager to advance our HOPE® program and are confident in the positive impact it will have on the lives of many.

For further information please contact

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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 noncancer pain as well as offering over the counter [OTC] products.

Zelira has established a special purpose vehicle (SPV) to conduct FDA Phase 1, Phase 2 and Phase 3 clinical trials for Zelira's proprietary and patent protected HOPE® 1. Zelira has contributed to the SPV its HOPE® 1 product, IP and real-world data for 55% equity ownership of the SPV. Cash investors will contribute a total of circa US$35 million to fund the SPV and US FDA trials for HOPE® 1 in exchange for a cumulative equity interest of 45% of the SPV. Zelira will manage the SPV as part of its business platform. The SPV has appointed iNGENū CRO Pty Ltd (iNGENū) as its Contract Research Organisation (CRO) to lead the clinical validation and regulatory registration of the study product with the US FDA through the submission of an Investigative New Drug (IND) application.

In May 2023, Zelira completed an IRB approved strategically designed multi-arm, head-to-head study targeting diabetic nerve pain. The clinical trial included a comprehensive comparison against the widely recognised and highly successful multi-billion dollar revenue generating drug Lyrica® (Pregabalin). With the findings underscoring the exceptional efficacy of our treatments in managing pain, with ZLT-L-007 demonstrating the most substantial reduction in pain severity, particularly at the 60-day and 90-day follow-up periods. 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.

Zelira's Rx business generates revenue from its proprietary medication, HOPE. The Company has two proprietary formulations under the HOPE® brand that are generating revenue in Australia, Washington, D.C., Pennsylvania and Louisiana. Zelira will also be expanding commercialisation of ZENIVOL® – the world's first clinically validated cannabinoid drug for treatment of chronic insomnia 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. Zelira also launched in 2021 the RAF FIVE™ brand, which consists of five OTC acne treatment products using a proprietary formulation incorporating cannabidiol (CBD).

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