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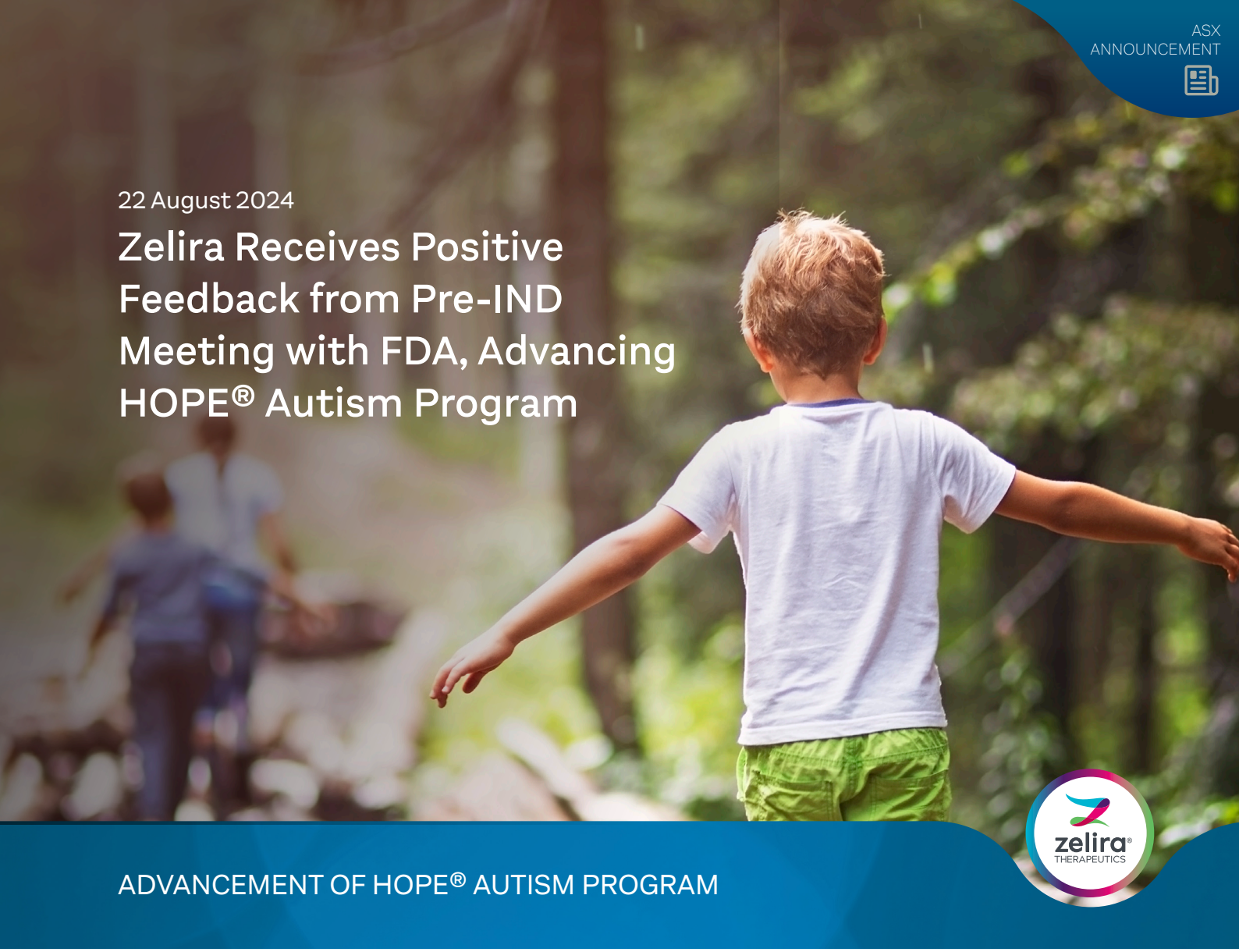
ANNOUNCEMENT



22 August 2024

Zelira Receives Positive Feedback from Pre-IND Meeting with FDA, Advancing HOPE® Autism Program

ADVANCEMENT OF HOPE® AUTISM PROGRAM

Key Highlights

- Zelira has received the official minutes from the FDA Pre-IND meeting.
- The FDA's positive feedback provided clarity on the strategic direction and design of Zelira's proposed clinical trials.
- The Company is now well-positioned to confidently move forward with its IND submission, further advancing the HOPE® program.

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) (Zelira), global leader in the development and commercialisation of clinically validated cannabinoid-based medicines, is pleased to announce that it has received the official minutes from the U.S. Food and Drug Administration (FDA) for the Pre-IND meeting held on 10 July 2024, for its HOPE® autism drug program.

Prior to the Pre-IND meeting, Zelira had already received clear and positive written responses from the FDA to its preliminary questions, which provided essential clarity and reinforced the FDA's support for the direction Zelira is taking with its HOPE® program.

The Pre-IND meeting was attended by key stakeholders, including the principals of iNGENu CRO. The meeting focused on the design of the IND-opening Phase 1 study in healthy volunteers, particularly on defining Zelira's target indication and patient population. The FDA offered valuable guidance on the study design, emphasising the importance of evaluating the safety and pharmacokinetics of the proposed doses of ZEL-HOP1. As a result of these discussions, Zelira has clearly defined the study's target population and endpoints, specifically focusing on treating Irritability associated with Autism Spectrum Disorder (ASD) in patients with Phelan-McDermid Syndrome (PMS).

The meeting minutes received from FDA reflect the positive and collaborative nature of the meeting, and confirm the clarity Zelira has gained regarding the next steps in its clinical development. The receipt of these minutes represents a significant milestone towards the Investigational New Drug (IND) submission, further advancing the HOPE® program. This also marks a significant step forward in the development of treatments for irritability associated with ASD and ensures a solid foundation for further clinical development of the program.

Dr Rob Jenny, Head of Regulatory Affairs at iNGENu CRO, commented on the significance of the FDA's official communication:

We are encouraged by the clarity and guidance provided by the Agency. This feedback not only provides validation of Zelira's approach but also the confidence to proceed with the next steps in its clinical program. We are excited to continue our collaboration as we move toward IND submission.

Dr. Oludare Odumosu, Global MD/CEO of Zelira Therapeutics expressed his enthusiasm

Receiving the official minutes from the FDA is a pivotal moment for our HOPE® program. The clear and detailed guidance provided empowers us to advance our clinical trials with a strong foundation and renewed confidence. This milestone is particularly significant as it brings us closer to developing a treatment specifically for individuals with Autism Spectrum Disorder (ASD) in the Phelan-McDermid Syndrome (PMS) target population. Our goal is to make a meaningful impact on the lives of those affected, and we are excited to continue advancing our mission to bring effective therapies to those with this unmet medical need.

Zelira is now poised to finalise its preparations for the Investigational New Drug (IND) submission, further advancing the HOPE® program's clinical development. The Company remains committed to bringing innovative and effective cannabinoid-based therapies to market, improving the quality of life for patients with ASD and their families.

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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**