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Zelira's HOPE® SPV Secures US$681,000 Fourth Funding Tranche to Drive FDA Program Milestones

FOURTH TRANCHE OF FUNDING RECEIVED

Key Highlights

- Receipt of fourth tranche of US$681,000 funding from the 2011 Forman Trust
- Total funds received by the HOPE® SPV now reaches US$3,250,000

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the development and commercialisation of clinically validated cannabis medicines, is pleased to announce, it has received the fourth tranche of US$681,000 of the US$3.25 million funding for Zelira to conduct FDA clinical trials for Zelira's proprietary and patent protected HOPE® 1 product. This funding, managed through a special purpose vehicle (SPV), follows the company's earlier ASX announcement dated 17 August 2023. The receipt of this tranche of funding from the 2011 Forman Trust brings the total funds received via the SPV to US$3.250 million. Zelira continues to manage the SPV as part of its business platform.

Zelira received clear and constructive feedback from the U.S. FDA during the Pre-IND meeting held on 10 July 2024. The FDA's official minutes confirmed support for the program and outlined key guidance for the design of the IND-opening Phase 1 study in healthy volunteers. The discussions with the FDA helped Zelira define the study's target population and endpoints, focusing on treating irritability in patients with Phelan-McDermid Syndrome (PMS) comorbid with Autism Spectrum Disorder (ASD). This represents an important step toward submitting the IND application and initiating clinical trials. The FDA's feedback highlights the potential of the HOPE® program to address significant unmet medical needs in patients with ASD and PMS.

Zelira expects to have subsequent rounds of closings from its continuing fund-raising efforts to support the HOPE® 1 formal FDA clinical program.

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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**