27 Feb 2020

Zelira's Phase 1 Clinical Trial in Patients on Long-Term Opioid Treatment Fully Enrolled. Emerald Clinics engaged as a Second Site.

- **Phase 1b Dose Escalation clinical trial now fully enrolled**
- **No serious adverse events reported to-date**
- **Emerald Clinics engaged as second site to accelerate recruitment**
- **Dosing to be completed by end of April 2020**
- **Study report expected by mid 2020**

Zelira Therapeutics Ltd (**ASX: ZLD, OTCQB: ZLDAF**) is pleased to announce that its Phase 1 Dose Escalation Trial in patients on long-term opioid treatment is now fully enrolled. No serious adverse events from dosing patients have been reported to date. Dosing is expected to be completed by April 2020 with the final report to be provided by mid 2020.

Prescription opioids for treating chronic pain are linked to serious side effects including physical dependence, which is an acknowledged growing global crisis. In the United States an estimated 49,000 people died from opioid overdose in 2017.

The Phase I trial is evaluating the safety and tolerability of whole plant extract following single and repeated doses with escalation in patients with chronic non-cancer pain on long-term opioid analgesia. Secondary outcomes include pharmacokinetics and the effects on pain, mood, sleep and opioid use over the duration of the trail.

The trial is being undertaken at the St Vincent's Hospital in Melbourne in conjunction with Emerald Clinics Ltd (**ASX: EMD**) in Perth who were recently engaged as a second site.

Zelira's Managing Director, Dr Richard Hopkins, commented, "*We are delighted to have achieved full enrolment, which represents a major milestone for the trial. We're also pleased for the opportunity to expand our partnership with Emerald Clinics by bringing them on as a second site. We have been impressed by their ability to complement the efforts of the St Vincent team by rapidly screening and enrolling eligible patients into trial.*

Dr Michael Winlo, CEO and Managing Director of Emerald Clinics said "*We are pleased to be working with Zelira, who are investing in the rigorous, product specific clinical studies required to bring cannabinoid based medical products into the mainstream where appropriate. Undertaking this trial validates our model of co creating evidence with our patients while providing high quality care.*

We are excited to be building upon the collaboration announced in 2019 and look forward to leveraging Real World Evidence (RWE) and traditional clinical trials to support Zelira's strategy and ultimately improve the health and wellbeing of our patients"

This announcement has been authorised by the Board.

Richard Hopkins
Managing Director

About Zelira Therapeutics (www.zeliratx.com)

Zelira Therapeutics Ltd is a leading global therapeutic medicinal cannabis company with access to the world's largest and fastest growing cannabis markets. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to enter global markets from 2020. The company is focused on developing branded cannabis products for the treatment of a variety of medical conditions.

The Company is undertaking product development programs targeting specific conditions (e.g. HOPE™) and human clinical trial programs focused on insomnia, autism and opioid reduction with activities in Australia and the USA.

The Company conducts this work in partnership with world-leading researchers and organizations including Complutense University in Madrid, Spain; Curtin University in Perth, Western Australia; the Telethon Kids Institute in Perth; the University of Western Australia, in Perth; St. Vincent's Hospital in Melbourne, Australia; and the Children's Hospital of Philadelphia (CHOP) in the United States.

Zelira has also formed a strategic partnership with European medicinal cannabis group HAPA Pharm BV, to access HAPA Pharm's EU-GMP grade manufacturing capabilities and accessing its German distribution network providing a credible and rapid path to commercialization for successful clinically validated formulations.

The Company has developed two proprietary formulations (HOPE™) already launched and generating revenues in Pennsylvania, has laboratory capabilities to develop formulations in Pennsylvania and Louisiana with ability to conduct clinical trials and is establishing a national footprint across the US for the licensing of its products.

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