



ASX Release

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Tickers:

Australia (ASX): ZLD
USA (OTCQB): ZLDAF

Ordinary Shares:
755,341,934

Options:
85,700,000

Zelda Granted Approval for Opioid Reduction Trial

- Trial at St Vincent's Hospital Melbourne to begin immediately with final results by Q4 2019
- First clinical trial designed with a primary end-point assessing the efficacy of cannabis in reducing opioid dependence
- Outcomes will feed in to larger Phase II trial

Zelda Therapeutics Ltd (ASX: ZLD, OTCQB: ZLDAF) Phase I Opioid Reduction Trial has been formally approved by the St Vincent's Hospital Ethics and Governance Committees.

The primary end-point is to assess the effectiveness of medicinal cannabis in reducing opioid dependence in patients with chronic non-cancer pain.

The Phase I trial will evaluate the safety and tolerability of whole plant extract following single and repeated doses in nine 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 trial.

The Phase I trial will commence immediately with preliminary results expected by late Q3 2019 and final results in Q4 2019.

The outcomes from the Phase I trial will inform a subsequent larger scale Phase II study that will assess the impact of oral whole plant extract on patient ability to tolerate a stepped opioid tapering protocol.

Prescription opioids 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.

Zelda's Managing Director, Dr Richard Hopkins, commented, "we're delighted to have the trial formally underway. To our knowledge, this is the first clinical trial to be designed with a primary end-point assessing the efficacy of a full spectrum plant-derived cannabis formulation containing THC and CBD to reduce opioid dependence in chronic non-cancer patients. If successful, the outcome of these trials will likely have immediate impact in major global markets where opioid overuse and addiction is a major problem."

The trial will be undertaken jointly with the prestigious St Vincent's Hospital in Melbourne.

Tim Slate

Company Secretary

About Zelda Therapeutics (www.zeldatherapeutics.com)

Zelda Therapeutics Ltd is an Australian-based bio-pharmaceutical company developing proprietary cannabinoid formulations to treat a variety of medical conditions. The Company is undertaking:

- **Human clinical trials** focused on insomnia, autism and opioid reduction with activities in Australia and the USA.
- **Preclinical research** to examine the effect of cannabinoids in breast, brain and pancreatic cancer and also diabetes-associated cognitive decline.

The company conducts this work in partnership with world-leading researchers and organisations 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

Zelda has also formed strategic partnerships with HAPA Medical BV, to access their EU-GMP grade manufacturing capabilities and their German distribution networks and Ilera Healthcare, a vertically integrated cannabis company with operations in Philadelphia and Louisiana. Together these partnerships provide access to over 110,000 registered medicinal cannabis patients globally for clinically validated Zelda products.