



ASX Release

7 November 2019

Zelda's Phase II Insomnia Clinical Trial Fully Enrolled

- **Australia's first clinical trial of medicinal cannabis to treat insomnia fully enrolled**
- **No serious adverse events reported to-date**
- **Dosing to be completed by December 2019**
- **Preliminary results expected by February 2020**

Zelda Therapeutics Ltd's (ASX: ZLD, OTCQB: ZLDAF) pioneering medicinal cannabis clinical trial for insomnia is now fully enrolled. No serious adverse events from dosing patients have been reported to date.

The insomnia trial is led by the prestigious University of Western Australia (UWA) Centre for Sleep Science (CSS) and is evaluating the safety and efficacy of a cannabinoid extract containing THC and CBD in patients with symptoms of clinically diagnosed chronic insomnia. The primary endpoint of the trial is to assess the impact of a full-spectrum cannabis extract on sleep.

This randomised, double-blinded, placebo controlled, cross over study is treating 24 patients with Zelda's proprietary insomnia formulation and a placebo formulation delivered sublingually. The medicine for the trial has been manufactured to pharmaceutical grade GMP standards by a Europe-based speciality manufacturer.

Dr Richard Hopkins, Zelda's Managing Director, said *"This is an important milestone for the trial. I acknowledge the hard work and dedication from the team at the UWA sleep centre.*

Should the trial be successful, the Company will move to immediately commercialise this formulation in all major global medicinal cannabis markets. Zelda's proposed merger with US-based Ilera Therapeutics will expand our access to the world's largest cannabis markets with approximately four million registered medicinal cannabis patients. Zelda's strategic partnership with European medicinal cannabis group HAPA Pharm BV also helps us access the world's fastest growing markets outside the US."

Dosing is on-track for completion by December 2019 with preliminary results expected by February 2020.

Tim Slate

Company Secretary

About Zelda Therapeutics (www.zeldatherapeutics.com)

Zelda Therapeutics Ltd is an Australian-based bio-pharmaceutical company developing a range of cannabinoid-based formulations for the treatment of a variety of medical conditions. The Company is undertaking:

- A **human clinical trial program** focused on insomnia, autism and opioid reduction with activities in Australia and the USA.
- A **pre-clinical research program** examining the effect of cannabinoids in breast, brain and pancreatic cancer as well as research examining the potential for cannabinoids to treat 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 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 commercialisation for successful clinically validated formulations.

On 9 October 2019, Zelda announced plans to merge with Ilera Therapeutics (Ilera), a privately held medicinal cannabis and cannabinoid science company based in the United States, which will be renamed Zelira Therapeutics Limited (Zelira). Subject to approval from Zelda shareholders, and all conditions of sale being met, Zelda is proposing to acquire 100% of Ilera Therapeutics through an all-scrip transaction.

The merger will create a leading global therapeutic medicinal cannabis company with access to the world's largest and fastest growing cannabis markets. The merger will bring together a world-class portfolio of revenue generating medicines and products undergoing clinical development that are expected to enter the market from 2020.

About Ilera Therapeutics LLC

Ilera Therapeutics LLC is a US-based company established by a team of experienced executives in the global bio-pharmaceutical sector. The Company is based in Pennsylvania and engaged in the development and formulation of proprietary, branded cannabis products and cannabinoids science focused on targeted medical and other indications.

The Team developed two proprietary formulations (HOPE™) already launched and generating revenues in Pennsylvania, has lab 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. The company also has a partnership with Ethicann for the development of a proprietary product, CAN-001, which is being developed for the treatment of chemotherapy-induced nausea and vomiting (CINV), which occurs in approximately 80% of the new 23.6 million cases of cancer annually worldwide.

ACN 103 782 378

For further information contact:

Contacts

Dr Richard Hopkins
Managing Director
+61 405 656 868

rhopkins@zeldatherapeutics.com

Monsoon Communications

Rudi Michelson
+61 3 9620 3333
rudim@monsoon.com

Registered Address

Level 26, 140 St Georges Terrace,
Perth Western Australia 6000
Tel: +61 8 6558 0886

E: enquiries@zeldatherapeutics.com