



ASX Release

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Tickers:

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

Ordinary Shares:

755,341,934

Options:

49,000,000

1,500,000 (\$0.04 – 6/2/2020)
*4,500,000 (\$0.04 – 6/2/2020)
1,000,000 (\$0.125 – 22/8/2021)
*2,000,000 (\$0.125 – 22/8/2021)

40,000,000 (\$0.03125 – 17/11/2021)

* subject to vesting conditions

First patient dosed in Zelda insomnia trial

- First patient dosed in pioneering insomnia trial
- Study led by one of Australia's leading sleep research centres
- Preliminary results expected 1H-2019

Zelda Therapeutics Ltd (ASX: ZLD, OTCQB: ZLDAF) announces that the first patient has received medication in its pioneering insomnia trial.

The clinical trial is being undertaken by the prestigious University of Western Australia (UWA) Centre for Sleep Science (CSS), which has state-of-the-art research facilities and is directed by Professor Peter Eastwood, National Health and Medical Research Council Senior Research Fellow.

The clinical trial is targeting patients with characteristic symptoms of chronic insomnia, which include difficulty falling and staying asleep on a long-term basis. A randomised, placebo controlled, cross over study design will be used to treat 24 patients with Zelda's medicinal cannabis formulation and a placebo formulation delivered sublingually. The medicine to be used in the trial has been manufactured to pharmaceutical grade GMP standards by a European-based speciality manufacturer.

The study will collect and analyse data to determine the effect of the Zelda formulation on the time it takes to fall asleep, time spent awake and asleep during the night and quality of sleep. In addition, subjective feedback from patients via standard questionnaires will be collected and analysed alongside the analytical data.

It is anticipated that preliminary results from this clinical trial will be available in the first half of 2019. Should the trial be successful, it is the intention to rapidly commercialise this formulation in markets where it is legal to do so.

Professor Peter Eastwood, Director, Centre for Sleep Science said, "We are delighted with this milestone and look forward to the next phase of the study. Should the trial be successful we see strong potential to provide a safe and effective medicine to patients with insomnia but also potentially for other sleep disorders."

Dr Richard Hopkins, Managing Director of Zelda said, "This is a major milestone for Zelda as it represents the first of a number of clinical trials we're planning to commence over the coming months. Positive data will enable Zelda to accelerate its commercialisation plans, which have been facilitated by our recent agreement with HAPA Medical to manufacture and distribute Zelda products in Germany and Europe."

Tim Slate
Company Secretary

About Zelda Therapeutics (www.zeldatherapeutics.com)

Zelda Therapeutics Ltd is an Australian-based bio-pharmaceutical company that is focused on developing a range of cannabinoid-based formulations for the treatment of a variety of medical conditions. The Company has a two-armed strategy comprising:

- A **human clinical trial programme** focused on insomnia, autism with activities in Australia, Chile and the USA.
- A **pre-clinical research programme** 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.

It has partnered with the world's leading cancer cannabis researchers at Complutense University Madrid in Spain to conduct certain pre-clinical work testing cannabis-based formulations known to have an effect in humans in order to generate data packs in a form expected by regulators and the pharmaceutical industry. A similar programme is in place with the Australian Telethon Kids Institute targeting paediatric brain cancer and Curtin University targeting pancreatic cancer and cognitive decline.

About University of Western Australia (UWA) Centre for Sleep Science (CSS) (www.sleepcentre.science.uwa.edu.au)

Western Australia has been a leader in Australian sleep medicine research for many years and through UWA's Centre for Sleep Science is at the forefront of sleep research and sleep education. Research conducted at the CSS at UWA aims to identify the causes of, and investigate therapies for, poor sleep. The CSS boasts five bedrooms equipped with state-of-the-art sleep recording and analysis equipment for laboratory-based research sleep studies. The CSS also contains a range of training and seminar rooms and is the base for a number of national postgraduate sleep training courses offered through the University of Western Australia. Members of the CSS regularly publish their research in leading international medical and scientific journals and present their work at national and international scientific meetings.