



ASX Release

29 November 2017

ZELDA THERAPEUTICS LIMITED
ACN 103 782 378

Level 45
108 St Georges Terrace,
Perth Western Australia 6000
Tel: +61 8 6558 0886
Fax: +61 8 6316 3337
E: enquiries@zeldatherapeutics.com
Web: www.zeldatherapeutics.com

Contacts

Corporate

Mr Harry Karelis
Executive Chairman
+61 413 056 328
hkarelis@zeldatherapeutics.com

Investors

Dr Stewart Washer
Executive Director
+61 418 288 212
swasher@zeldatherapeutics.com

Directors

Mr Harry Karelis
Dr Stewart Washer
Ms Mara Gordon
Mr Jason Peterson

ASX Code:

ZLD

Ordinary Shares:

754,841,934

Options:

48,000,000

6,000,000 (\$0.04 - 6/2/2020 -
subject to vesting conditions)
2,000,000 (\$0.04 - 6/2/2020)
40,000,000 (\$0.03125-17/11/2021)

Australian Regulators Approve Zelda's Insomnia Clinical Trial

- **Australia's first medicinal cannabis trial for insomnia is approved**
- **Clinical trial approval granted from the Therapeutics Goods Administration and the Human Research Ethics Committee**
- **WA Health Department grants approval for the supply and prescription of Zelda's medicinal cannabis formulations for the clinical trial**
- **Zelda's formulations for the clinical trial to be manufactured by Eurofins Sinensis, a leading European GMP manufacturing pharmaceutical company**
- **Insomnia clinical trial on track to commence in Q1 2018, with patient recruitment expected to commence shortly**

The Board of **Zelda Therapeutics Ltd (ASX: ZLD, Zelda or the Company)** is very pleased to announce it has received full regulatory approval to commence a clinical trial of its medicinal cannabis formulations on chronic insomnia patients in Australia. The clinical trial will be 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 Company has been focused on targeting its medicinal cannabis formulations to treat a number of disease conditions, and progress its research to clinical trials, the first being chronic insomnia. Zelda has access to patient data in the US and Chile, which shows anecdotal evidence of benefit from medicinal cannabis when used to treat insomnia. Based on this data and other studies on the safety of medicinal cannabis, the Company has worked with the research team at UWA to develop a rigorous research trial protocol to study the clinical efficacy of its insomnia formulations.

Zelda's clinical trial will target a sample population of people 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, where patients are selected at random to be treated with Zelda's medicinal cannabis formulation or a placebo formulation.

Zelda's clinical trial protocol was submitted to the relevant regulatory bodies in Australia and have received full approval from the Human Research Ethics Committee and Therapeutics Goods Administration (TGA), the governing body for therapeutics. Furthermore, approvals were granted from the Western Australian Department of Health to allow clinicians to prescribe the formulation for the trial. The medicinal cannabis formulation for the clinical trial is being manufactured to Good Manufacturing Practice (GMP) standards by a global leader in pharmaceutical manufacturing - Eurofins Sinensis, based in The Netherlands.

It is anticipated that the clinical trial will formally commence in the first quarter of 2018, with patient recruitment expected to commence shortly.

Clinical trials are a key research tool for advancing medical knowledge and patient care. Obtaining regulatory approval to commence this clinical trial is a major milestone for the Company which continues to make significant progress on its pipeline of other research activities. Preliminary results from the insomnia clinical trial are anticipated by Q3 2018, and if positive the Company will be well positioned to progress commercialisation activities for this formulation.

Harry Karelis, Executive Chairman said *“This is a very exciting milestone for Zelda. We have been meticulously working our way through the regulatory framework to ensure we achieve all necessary approvals. This has been a very rigorous process and has taken some time but we are now very well positioned and are the first to undertake a clinical trial of this nature in Australia. We are very pleased to have partnered with the leading researchers in this field at the prestigious UWA Centre for Sleep Science, and are confident this clinical trial will deliver the high-quality data we need to further develop and commercialise our medicinal cannabis formulation.”*

Professor Peter Eastwood, Director, Centre for Sleep Science said *“Population-based data show that about one third of adults have regular difficulty getting to sleep or staying asleep¹. We are very excited to be conducting this trial sponsored by Zelda Therapeutics, which will be an Australian first for investigating medical cannabis as a potential treatment for sleep disorders due to insomnia. Australia has been a leader in sleep medicine for many years and our Western Australia based Centre comes equipped with state-of-the-art sleep recording and analysis equipment. For this trial we have assembled a team of experts including sleep physiologists, sleep physicians and clinical psychologists.”*

About Zelda Therapeutics (www.zeldatherapeutics.com)

Zelda Therapeutics (“Zelda”) 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-pronged strategy comprising:

- A human clinical trial programme focused on insomnia, autism and eczema with activities in Australia and Chile.
- A pre-clinical research programme examining the effect of cannabinoids in breast, brain and pancreatic cancer. 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.

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

Western Australia (WA) 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.

¹ Asleep on the job: costs of inadequate sleep in Australia. Published by the Sleep Health Foundation in August, 2017