



**Teleconference tomorrow 11:30am AEST Wednesday 8 April 2020**

**Conference ID: 10005625**

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**1800 908 299**

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## **Media Release**

# **Zelira Therapeutics' Medicinal Cannabis Product Stars in Insomnia Clinical Trial**

**7 April 2020, Perth, Australia:** Zelira Therapeutics has achieved a world-first clinical validation demonstrating that its medicinal cannabis drug works for people suffering insomnia. This paves the way for selling into global markets from the second half of this year including in the USA.

The Perth-based company has put its patented medicinal cannabis formulation ZLT-101, ingested sublingually, through a Phase 1b/2a clinical trial against insomnia, and seen it pass with flying colours.

“We are delighted as these results have exceeded our expectations,” said Dr Richard Hopkins, Managing Director, ex-US markets, at Zelira Therapeutics. “Globally we are the first company to take a full-spectrum cannabis product and test it for efficacy in the insomnia space.”

Not only do the results mean that Zelira can launch a product for insomnia, Dr Hopkins said the data – and the clinical validation – from the trial mean that doctors can be confident in prescribing medical cannabis.

“We have given physicians the clinical evidence to prescribe this compound,” he said. “There are very few cannabis products that can do that today. Based on the success of this trial, we’re on-track to launch our Insomnia product into global markets early in the second half of 2020, and expect to be earning revenues soon after.”

**Trial Patient “I have fallen asleep + not woken up in the middle of the night: more so than ever in the past 22 years so am fairly confident I’ve been on active medication”**

The trial used a randomised, double-blind, cross-over design where patients were treated for 14 nights with ZLT-101 and 14 nights with placebo, separated by a one-week washout period. The trial was undertaken at the world-leading University of Western Australia (UWA) Centre for Sleep Science (CSS). Conducted over September 2018-December 2020, the trial involved 23 volunteer patients with chronic insomnia being treated with ZLT-101.

To qualify for the trial the patients had to be suffering clinically diagnosed chronic insomnia: this means that they displayed characteristic symptoms of chronic insomnia, which include difficulty falling asleep, and/or in staying asleep on a long-term basis.

## The trial successfully achieved all its primary and secondary endpoints

ZTL-101 treatment was shown to be safe, as measured by participants reporting only minor adverse events. These included dry mouth and headache with 96% of symptoms resolving by the next morning. In addition, patients tolerated the maximal dose well.

In terms of efficacy, results showed that ZTL-101 treatment significantly improved key insomnia symptoms.

Treated patients showed 26% improvement in their Insomnia Severity Index (ISI) scores – a current standard for measuring effectiveness of insomnia treatments – while patients on the highest dose achieved a 36% improvement in symptoms.

Analysis of secondary endpoints showed treated patients slept significantly longer, went to sleep faster and went back to sleep sooner after waking.

Patients also reported significant improvement in quality of life measures including feeling rested after sleep, feeling less stressed, less fatigued and improved overall functioning.

The Principal Investigator for the study, Professor Peter Eastwood, Director at the Centre for Sleep Science at UWA, said the study represents the most rigorous clinical trial ever undertaken to assess the therapeutic potential of medicinal cannabis to treat chronic insomnia.

“The fact that ZLT-101 treatment achieved statistically significant, dose-responsive improvements across a broad range of key insomnia indices is impressive,” said Professor Eastwood. “And the significant improvement in subjective sleep quality and feelings of waking up rested as reported by participants was particularly notable. Positive patient experiences are critical to the success of any insomnia drug, and highlights the potential for ZLT-101 to address a key area of unmet need.”

“Taken together, these results are comparable to other approved insomnia therapies at a similar stage of development and suggests that ZLT-101 can be developed as a novel treatment for chronic insomnia. This is a very exciting outcome.”

Insomnia is a large unmet medical need. It affects ~30% of the US population and is a major risk factor for patients suffering chronic pain, neurological disorders (Parkinson’s, dementia), mental disorders (anxiety, depression, anorexia) and cardiovascular disease.

The market for prescription and over-the-counter medications to treat the condition in the US generates more than US\$2 billion (A\$3.3 billion) in annual revenue. As well as the US, Zelira will also aim to supply its insomnia formula in other markets where medicinal cannabis has been legalised including the US Australia, Germany and the UK.

## Global launch of Zelira’s Insomnia product on-track for second half of 2020

These positive results add ZLT-101 to the portfolio of Zelira products being commercialised including the recently launched HOPE™ range, in global markets including the US, Australia, Germany and the UK. The company is also undertaking further human clinical trials for autism and opioid reduction, and is on-track to bring additional products for aged care (Parkinson’s) and oral-healthcare to market later in 2020.

## Conference call details

Time: 11:30 AEST on Wednesday 8 April

Conference ID: 10005625

It is strongly recommended that you access the call through pre-registration, but dial in numbers are also included below:

|  |                  |               |                |
|--|------------------|---------------|----------------|
| <b>1. Pre-registration</b><br>Participants can pre-register by navigating to: <a href="https://s1.c-conf.com/diamondpass/10005625-invite.html">https://s1.c-conf.com/diamondpass/10005625-invite.html</a><br>Registered participants will receive their dial in number upon registration to enter the call automatically on the day. |                  |               |                |
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**Address**

Level 26  
140 St Georges Terrace  
Perth WA 6000  
AUSTRALIA  
Tel: +61 8 6558 0886  
Fax: +61 8 6316 3337  
E: enquiries@zeliratx.com  
W: www.zeliratx.com  
ACN 103 782 378

**Tickers**

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

**Australia Contacts:**

Dr Richard Hopkins  
Managing Director & CEO, Ex USA  
+61 405 656 868  
rhopkins@zeliratx.com  
Level 26, 140 St Georges Terrace  
Perth WA 6000  
AUSTRALIA

**Monsoon Communications**

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

**U.S. Contacts:**

Dr Oludare Odumosu  
Managing Director & CEO, USA  
+1 909 855 0675  
oodumosu@zeliratx.com  
3553 West Chester Pike #110  
Newtown Square PA 19073  
UNITED STATES OF AMERICA

**GVM Communications, Inc.**

Gia Morón  
+1 347 678 8079  
gia@gvmcommsinc.com