19 Feb 2020

Teleconference 11am (AEDT) today with

Osagie Imasogie, Zelira Chairman

and Dr Richard Hopkins, Managing Director-ex USA

Toll free dial-in (Australia): 1800 908 299

Conference ID: 10004335

(more dial in options p5)

Zelira Therapeutics Meets Primary Endpoints for Phase (1b/2a) Medicinal Cannabis Trial for Insomnia

- **23 chronic insomnia patients treated with ZLT-101, Zelira's proprietary and patented medicinal cannabis formulation, demonstrated statistically significant improvement in Insomnia Severity Index scores compared to placebo**
- **ZLT-101 therapy was well tolerated, with no serious adverse events reported**
- **Positive trial results an important milestone for Zelira**
- **Poised to launch world's first clinically validated medicinal cannabis product for insomnia in 2020**
- **Expands Zelira's product portfolio alongside the HOPE™ product range**

Zelira Therapeutics Ltd (**ASX: ZLD, OTCQB: ZLDAF**), a global leader in the development of clinically validated cannabis medicines, today announced positive Phase 1b/2a results confirming that ZLT-101 therapy achieved the primary endpoint of a statistically significant improvement in Insomnia Severity Index scores in patients diagnosed with chronic insomnia.

The Phase 1b/2a trial recruited 24 chronic insomnia patients, aged between 25-70. The study was a randomised, double-blind, cross-over design involving 14 nights of ZTL-101 and 14 nights of placebo, separated by a one-week washout period. All participants underwent a monitored sensitivity test to a mixture of ZTL-101 and placebo prior to commencing dosing. When dosing commenced each participant was able to take a single (0.5ml of 11.5mg total cannabinoids) or double (1 ml of 23mg total cannabinoids) dose of the medication, delivered sublingually, according to their symptoms.

Of the 23 participants who completed the protocol, 12 (52%) chose to increase the ZTL-101 medication from a single dose (0.5ml/11.5mg total cannabinoids) to double dose (1.0ml/23mg total cannabinoids) of ZTL-101 (as measured on the 14th night). Sixteen participants (69.5%) were taking a double dose (1.0ml) of the placebo on the 14th night.

The primary study endpoints were: (1) safety of the medication based on adverse event reporting; and (2) insomnia symptoms as measured by the Insomnia Severity Index (ISI) at the end of each of the 14 night active medication/placebo periods.

Primary Endpoint 1: Safe and Well Tolerated

A total of 36 non-serious adverse events possibly or likely related to ZTL-101 medication were recorded from 17 participants. The most frequently reported adverse event was xerostomia (dry mouth) (22.2% of all events) followed by dizziness (16.7%), headache (11.1%) and feeling abnormal (11.1%).

A total of 4 non-serious adverse events were recorded from 4 participants during dosing of the placebo medication. Headache was most frequently reported (50%) followed by dizziness (25%) and variable mood (25%).

All adverse events were classified as mild and had either resolved (97.5%) overnight or soon after waking each day or were resolving at the end of the trial.

Primary Endpoint 2: Significant Change in ISI Scores

Compared to baseline ISI scores (18.0±3.7) a significant decrease was observed following ZTL-101 (12.9±5.3, $p<0.001$) but not following placebo (18.0±4.3, $p>0.05$) (Figure 1 attached). The magnitude of decrease in ISI scores following ZTL-101 and placebo were 5.2±4.3 [Confidence Interval (CI) = 3.4 to 7.0] and 0.0±3.3 [CI = -1.8 to 1.9], respectively. The ISI scores following ZTL-101 and placebo were significantly different ($p<0.001$).

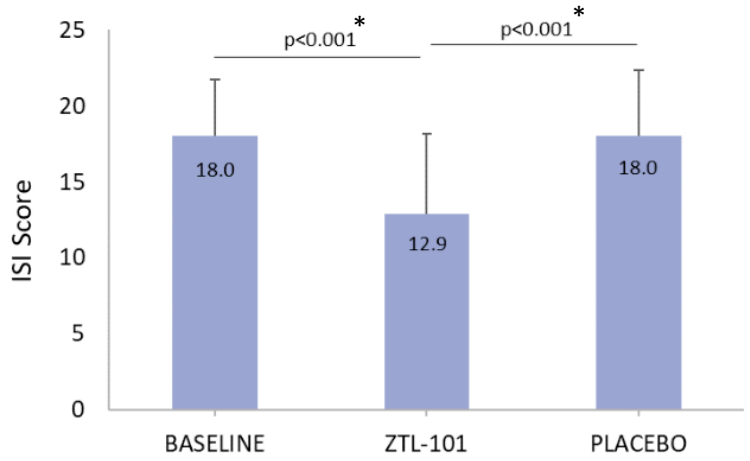

Figure1. Group mean Insomnia Severity Index (ISI) scores (n=23).

Error bars are one standard deviation

*significant difference

"*This study represents the most rigorous clinical trial ever undertaken to assess the therapeutic potential of medicinal cannabis to treat the symptoms of chronic insomnia. It's also the first trial to use the Insomnia Severity Index, arguably the current gold standard in this field, to measure the efficacy of a medicinal cannabis product to treat insomnia symptoms. The fact that ZLT-101 treatment achieved a statistically significant improvement in ISI scores is very impressive, particularly given the relatively short two-week dosing window. The lack of serious adverse or persistent mild adverse events is also encouraging given the reported safety issues for several already approved insomnia therapies. Taken together, these results suggest ZLT-101 has potential as a novel treatment for Insomnia."* commented **Professor Peter Eastwood, Principal Investigator for the study**, and Director at the Centre for Sleep Science at the University of Western Australia.

Dr Richard Hopkins, Managing Director ex-US markets said "*We are delighted with the preliminary findings from this study. Additional analyses are on-going and we expect to release a final report, including data from a comprehensive suite of secondary endpoints, by the end of March 2020 and thereafter, subsequent scientific publications based on the positive results from this study. We would like to acknowledge the dedicated team at the UWA Sleep Centre and express our gratitude to the patients and supporting investigators/organisations who participated in the study."*

An estimated 70 million Americans have insomnia where the market for prescription and over-the-counter medications used to treat the condition generates over US$2 billion in annual revenue. Zelira is leading the development of clinically validated full spectrum cannabis medicines to access global markets for insomnia medications.

Osagie Imasogie, Chairman of Zelira, commented *"The positive outcome to this trial represents an important milestone for Zelira and its commitment to address the unmet need for clinically validated cannabis medicines and offer more treatment options to physicians and patients. Having successfully completed its recent merger, Zelira is now poised to rapidly commercialise the world's first clinically validated cannabis medicine for insomnia into global markets in 2020, including the US, based on the positive results of this study.*

These positive results add ZLT-101 to the Zelira portfolio of commercialized and to be commercialized, revenue generating products derived from cannabinoids, such as HOPE™, in the US and globally, as a result of rigorous scientific work by the Zelira team. Zelira will continue to deploy its unique Launch, Learn and Develop strategy to launch more scientifically validated products, targeting various conditions, into the market in 2020."

Next Steps:

A final report from the clinical study including an analysis of a comprehensive suite of secondary endpoints will be provided by end of March 2020. These results will inform the design of any future clinical studies.

Zelira will also seek to deploy its Launch, Learn and Develop strategy to commence supply of its clinically-validated insomnia formula in countries and states where medicinal cannabis has been legalised including Australia, the USA, Germany and the United Kingdom.

This announcement has been authorised by the Board.

Richard Hopkins
Managing Director

About Zelira Therapeutics (www.zeliratx.com)

Zelira Therapeutics Ltd is a leading global therapeutic medicinal cannabis company with access to the world's largest and fastest growing cannabis markets. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to enter global markets from 2020. The company is focused on developing branded cannabis products for the treatment of a variety of medical conditions.

The Company is undertaking product development programs targeting specific conditions (e.g. HOPE™) and human clinical trial programs focused on insomnia, autism and opioid reduction with activities in Australia and the USA.

The Company conducts this work in partnership with world-leading researchers and organizations 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.

Zelira 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 commercialization for successful clinically validated formulations.

The Company has developed two proprietary formulations (HOPE™) already launched and generating revenues in Pennsylvania, has laboratory 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.

Conference call details

Time: 11 am (AEDT) Wednesday 19 February
Conference ID: 10004335

Access the call by one of two ways:

1. **Pre-registration** Participants can pre-register by navigating to: https://s1.c-conf.com/diamondpass/10003237-invite.html. Registered participants will receive their dial in number upon registration to enter the call automatically on the day.			
2. Dial-in directly (toll free)			
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