

## **Zenivol™ launches in Australia after TGA adds to Special Access Scheme**

**16 September 2020**

- **Zenivol is now available for prescription to patients through the Therapeutic Goods Administration (TGA) Special Access Scheme**
- **Zenivol™ is a leading proprietary cannabinoid medicine supported by clinical trial data in patients with chronic insomnia**
- **Zenivol™ is available for immediate supply via its distribution partner Health House**
- **The Australian launch is a key milestone to commercialise Zenivol™ in global markets**
- **Zelira on-track to complete the launch of five new products in global markets in 2020**

**Zelira Therapeutics Ltd (ASX: ZLD, OTCQB: ZLDAF)** is pleased to announce that its proprietary cannabinoid medicine Zenivol™ can now be prescribed to patients in Australia through the Therapeutic Goods Administration's (TGA) Special Access Scheme and via Authorised Prescribers. Zenivol™ is available for immediate supply via Zelira's national distribution partner Health House<sup>1</sup>.

Zelira recently successfully completed a world-first; a clinical trial powered to show statistical significance through a randomised, double-blind, cross-over designed Phase 2A clinical study in patients suffering from chronic insomnia treated with Zenivol™. The results confirmed that Zenivol™ is a safe and effective therapy for chronic insomnia.

Zenivol™ treatment significantly improved key insomnia symptoms, as measured using the Insomnia Severity Index (ISI) - a current standard for measuring effectiveness of insomnia treatment, and was not associated with any serious adverse events. This trial was conducted at the world-class University of Western Australia (UWA) Centre for Sleep Science.

Analysis of secondary endpoints showed patients treated with Zenivol™ slept longer, went to sleep faster and went back to sleep sooner after waking. Patients also reported statistically significant improvements in quality of life measures including feeling rested after sleep, feeling less stressed, less fatigued and improved overall functioning.

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<sup>1</sup> ZLD ASX announcement 21 November 2019

**Dr Richard Hopkins, Managing Director ex-USA** said *“Zelira is delighted to launch Zenivol™ in the Australian market as a leading clinically-validated cannabinoid-based treatment for chronic insomnia. Zenivol™ is custom designed to address the large unmet need for insomnia patients that have failed current medications and are looking for a safe and effective alternative. The ability to support Zenivol™ with clinical trial data provides a key point of differentiation in the market and further supports our global Zelira commercialisation strategy.*

*Zelira’s ability to launch Zenivol™ just five months after completing a clinical trial highlights the speed we can bring products to market using our unique ‘Launch Learn and Develop’ strategy. I would like to acknowledge the fantastic efforts of the Zelira team and our collaborators from the University of Western Australia who conducted the clinical trial, all of whom have made this launch possible.”*

This announcement has been approved and authorised for release by the board of Zelira Therapeutics Limited.

**Richard Hopkins**  
**CEO & Managing Director ex-USA**

**About Zelira Therapeutics ([www.zeliratx.com](http://www.zeliratx.com))**

Zelira Therapeutics Ltd is a leading global therapeutic medical 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 including insomnia, autism and chronic non-cancer pain.

The Company has two proprietary formulations under the HOPE™ brand that are generating revenues in Pennsylvania and have been licensed in Louisiana with other states in the US expected to follow. Zelira has also developed Zenivol™ - a leading cannabinoid-based medicine for treatment of chronic insomnia. Zenivol™ has successfully completed the worlds first Phase 2a clinical trial for chronic insomnia where it was found to be a safe and effective treatment. Zenivol™ was successfully launched in Sept 2020.

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

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