

Zelira Therapeutics Ltd

12:58 16 Sep 2020

Zelira Therapeutics launches Zenivol™ product in Australia after TGA adds to Special Access Scheme

Zelira Therapeutics Ltd's (ASX:ZLD) (OTCMKTS:ZLDAF) 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.

The Australian launch is a key milestone to commercialise Zenivol™, a leading proprietary cannabinoid medicine supported by clinical trial data in patients with chronic insomnia, in global markets.

Zenivol™ is available for immediate supply via Zelira's national distribution partner Health House.

"Custom designed"

Managing director ex-USA Dr Richard Hopkins 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."

Shares have been as much as 17% higher to A\$0.07 intra-day and have risen from A\$0.05 at the market close on August 13.

Successful clinical trial

Zelira recently successfully completed a world-first 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™.

These results confirmed that Zenivol™ is a safe and effective therapy for chronic insomnia.

The 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.

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.

Commercialisation strategy

The Australian launch is a key milestone to commercialise Zenivol™ in global markets.

Price: 0.066

Market Cap: \$75.39 m

1 Year Share Price Graph



Share Information

Code: ZLD

Listing: ASX

52 week High Low
0.087 0.022

Sector: Cannabis

Website: www.zeldatherapeutics.com

Company Synopsis:

Zelira Therapeutics Ltd (ASX:ZLD) is a leading global therapeutic medical cannabis company with access to the world's largest and fastest growing cannabis markets.

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Dr Hopkins said: "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."

Zelira remains on-track to complete the launch of five new products in global markets in 2020.

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