



## **Zelira Signs Real-World Data Agreement for Insomnia Drug Zenivol™ with Emyria**

**30 September 2020**

- **Leverages Emyria’s clinical and data expertise to monitor the safety and efficacy of Zenivol™ treatment in patients diagnosed with chronic insomnia**
- **Real-world data will complement existing clinical data for Zenivol™ and inform path to further development and product registration**
- **Data will add further value to the global commercialisation opportunities for Zenivol™**
- **Partnership reinforces Zelira’s competitive advantage for bringing high-value cannabinoid medicines to market supported by clinical and real-world patient data**

**Zelira Therapeutics Ltd (ASX: ZLD, OTCQB: ZLDAF)** is pleased to announce it has entered into an agreement with Emyria Ltd (ASX:EMD), (formerly Emerald Clinics), a leader in the collection and translation of real-world patient data, to collect data from patients treated with Zenivol™ in Emyria’s network of specialist medical clinics.

Under the terms of the agreement Emyria will provide access to real-world longitudinal data collected from patients prescribed Zenivol™ for treatment of chronic insomnia and related conditions. De-identified patient data will include details regarding diagnosis and co-morbidities, concomitant medications, dosages prescribed to patients and their responses to Zenivol™ treatment assessed using various clinical and subjective endpoints including the Insomnia Severity Index (ISI) questionnaire.

Real-world data and information collected from patients will complement the existing clinical data-pack for Zenivol™ and be used to inform further clinical development and, ultimately, the path to product registration.

Zelira will pay Emyria an upfront fee of \$50,000 along with a subscription fee for each patient enrolled in the study, up to a maximum of 100 participants. The term of the agreement is for 12 months with an option to extend the subscription fees on an ongoing basis.

**Zelira’s Managing Director, Richard Hopkins**, said, *“Australia’s commitment to developing a highly regulated market for prescription cannabis medicines means this country is a global leader in collection of high-quality real-world data relating to patients treated with medicinal cannabis. We believe Emyria’s approach to collection and curation of patient data, underpinned by its clinical services, is best-in-class.*

*Being able to access real-world data, in real-time, from patients treated with Zenivol™ will have immediate benefit for our go-to-market strategy. This information will also inform the design of future clinical trials, reduce the risks and costs of development and accelerate the path to regulatory approval.*

*These key value-adding features highlight the competitive advantages of our unique 'Launch, Learn and Develop' model, further differentiating Zelira from its global peers enhancing the commercialisation opportunities for the Company."*

**Emyria's Chief Executive Officer, Dr Michael Winlow,** said: *"We're delighted to be working with Zelira Therapeutics, to realise the potential for a real-world evidence asset that will help to progress the commercialisation and regulatory acceptance of its medicinal cannabis products. Partnering with clinically-focused companies, such as Zelira, further supports our model of generating high-quality patient data to accelerate development of unregistered medicines for patients."*

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 world's 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.

**About Emyria ([www.emyria.com](http://www.emyria.com))**

Emyria Limited is a Real-World Evidence data company using its network of specialist clinical services and purpose-built, remote patient monitoring technologies and data platforms to accelerate the development and registration of new treatments and facilitate the implementation of valuable new care models. Emyria's model provides high quality care for patients with unmet needs while also generating high quality and ethically sourced clinical data. Emyria's evidence is used by Emyria's customers pay for insights, conduct clinical trials and accelerate medical innovation.

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