

# Zelira Partners with Emyria for Autism Observational Trial for HOPE<sup>™</sup> Products

# 9 November 2020

- Observational Trial will collect efficacy and safety data from patients diagnosed with Autism Spectrum Disorder (ASD) that have been prescribed one or more HOPE<sup>™</sup> products
- Leverages Emyria's real-world data expertise and provides access to Emyria's national network of clinics Emerald Clinics to facilitate patient access
- Complements existing HOPE<sup>™</sup> data to inform development and evaluation of a path to registration
- Accelerates global commercialisation opportunities for HOPE<sup>™</sup> products
- 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), to conduct an Observational Trial for patients diagnosed with Autism Spectrum Disorder (ASD) treated with Zelira's HOPE<sup>™</sup> range of products. Emyria is recognised as a global leader in the collection and translation of real-world patient data (RWD) and also owns and manages a national network of specialist medical clinics.

The Observational Trial will be one of the largest medicinal cannabis studies ever undertaken involving a specific range of products in patients diagnosed with ASD. The study design will facilitate strategic engagement with key stakeholders in the Autism community and streamline patient access via Emyria's national network of specialist medical clinics – Emerald Clinics. These efforts will complement and augment the recent launch of HOPE<sup>™</sup> in the Australian market.

Under the terms of the agreement, Emyria will provide Zelira with longitudinal RWD collected from ASD patients prescribed a HOPE<sup>™</sup> product. Data will include patient's efficacy and safety relating to comorbidities, concomitant medications, dosing information and patient responses to HOPE<sup>™</sup> treatment as measured using standard ASD clinical and behavioural endpoints.

Zelira will pay Emyria fees of \$115,000 in two instalments over the first 6 months as well as a subscription fee for each patient enrolled in the study, up to a maximum of 150 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, "We are excited to secure this agreement with Emyria to further augment our launch of  $HOPE^{T}$  in Australia, particularly after the successful launch of these products in the USA.

This will be one of the largest observational medicinal cannabis studies ever undertaken in patients with ASD involving a specific range of products. This focussed approach will generate very high-quality RWD that will complement our existing data-pack for HOPE<sup>m</sup> and inform our global marketing strategy in real-time. This information will also inform the design of possible future clinical trials, reduce the risks and costs of development and accelerate the path to regulatory approval.

This agreement builds upon our existing partnership with Emyria by further leveraging their leading RWD expertise. Emyria's ability to expand and adapt their model to facilitate a large Observational Trial highlights the strategic value of this relationship. These key value-adding features highlight the competitive advantages of our unique 'Launch, Learn and Develop' model, further differentiating Zelira from its global peers, and enhancing the commercialisation opportunities for the company."

**Emyria's Managing Director, Dr Michael Winlo,** said: "We're delighted to be working with Zelira Therapeutics again, this time to realise the potential of our real-world evidence data products to help progress the commercialisation and regulatory understanding of Zelira's medicinal cannabis treatments. Partnering with clinically-focused companies, such as Zelira, further supports our model of generating high-quality patient data to accelerate development of improved cannabis medicines for patients with unmet needs."

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)

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.

The Company is undertaking product development programs targeting specific conditions and human clinical trial programs focused on insomnia, autism and opioid reduction in patients with chronic non-cancer pain.

The Company has developed two proprietary formulations (HOPE<sup>™</sup>) targeting Autism Spectrum Disorder already launched and generating revenues in Pennsylvania and Louisianna and Australia. Zelira has also launched Zenivol<sup>™</sup> in Australia as the worlds leading clinically validated proprietary formulation for treatment of chronic insomnia.

The Company conducts this 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)

Emyria Limited creates data products from robust and ethically sourced Real-World Evidence (RWE) gathered across its specialist clinical network - **Emerald Clinics (www.emeraldclinics.com.au).** Emyria's data products – **Emyria Registration** and **Emyria Pharmacovigilance** - accelerate the development and registration of new and promising treatments for patients with unmet medical needs by providing unique, real-world insights into treatment safety, quality and efficacy. Emyria's data assets are also a source of unique IP for Emyria. In addition, Emyria creates remote patient monitoring technologies, data platforms and care models that further improve the quality of its RWE data assets and insights.

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