

ASX Release

09/11/2020

## Emyria enters data deal with Zelira to support Autism trial

### Highlights:

- **Observational trial will collect efficacy and safety data from patients with Autism Spectrum Disorder (ASD) that have been prescribed one or more HOPE™ products**
- **Leverages Emyria's real-world data expertise and national network of clinics – Emerald Clinics - to facilitate patient access**
- **Emyria data to inform product development and evaluation of a path to registration**
- **Partnership highlights the value of Emyria's clinical and real-world patient data to support treatment development for patients with unmet needs**

**Emyria Limited (ASX: EMD) (Emyria or the Company)**, a company that accelerates treatment development and elevates care for patients with unmet needs, is pleased to announce that it has been selected to conduct an observational trial for patients diagnosed with Autism Spectrum Disorder (ASD) treated with Zelira's HOPE™ range of products.

**Emyria's Managing Director, Dr Michael Winlo**, said: "We're delighted to be working with Zelira Therapeutics again, this time to apply our real-world evidence data products and trial-ready clinical network to help progress the commercialisation and regulatory understanding of Zelira's medicinal cannabis treatments in an area of unmet clinical need. 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."

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™ in the Australian market.

Under the terms of the agreement, Emyria will provide Zelira with real-world longitudinal data collected from ASD patients prescribed a HOPE™ product. Data will include efficacy and safety insights relating to co-morbidities, concomitant medications, dosing information and patient responses to HOPE™ treatment as measured using standard ASD clinical and behavioural endpoints.

Zelira will pay Emyria fees of \$115,000 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™ in Australia, particularly after the successful launch of these products in the USA.

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# emyria

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 data that will complement our existing data-pack for HOPE™ 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 real-world data 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, enhancing the commercialisation opportunities for the company."

This announcement is approved and authorised for release by the Board of Emyria Limited.

## For further information

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

Emyria Limited creates unique data products that accelerate the development of new treatments for patients with unmet needs. Emyria achieves this by analysing the deep, deidentified clinical data gathered from its specialist clinical network – **Emerald Clinics** ([www.emeraldclinics.com.au](http://www.emeraldclinics.com.au)) – and turning that into Real-World Evidence (RWE). Emyria's data products accelerate the development and registration of new and promising treatments for patients with unmet medical needs by providing unique, real-world insights into the safety, quality and efficacy of those unapproved treatments, in real patients in the community. Emyria's data assets are also a source of unique IP for Emyria, which along with its remote patient monitoring technologies, data platforms and care models, further improve the quality of its RWE data assets and insights as well as the care provided to patients.

## 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.

## Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represents the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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