ASX ANNOUNCEMENT

17 May 2022

HOPE® 1 demonstrates improvements in Global Clinical Impression (CGI) in patients with autism spectrum disorder (ASD)

HOPE® 1 LONGITUDINAL, REAL-WORLD DATA TRIAL IN AUTISM SPECTRUM DISORDER SUPPORTS SAFE AND EFFECTIVE USE

Key Highlights

- Results of longitudinal, real-world data (RWD) from 45 patients with autism spectrum disorder (ASD) using HOPE® 1 supports its safe and effective use.
- The Clinician Global Impression (CGI) rating scale improved with duration of use.
- Results show that almost 70% of patients in the study cohort were rated by clinicians as having achieved at least 'moderate' therapeutic effect after 5 months on HOPE® 1.
- An effective dosing range was established for both paediatric and adult ASD patients based on the results of this study.
- Completes the observational trial conducted in partnership with Emyria.
- This data will be used to support the design of future interventional clinical trials with HOPE® 1.

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the research, development and commercialisation of clinically validated cannabinoid-based medicines, is pleased to announce that it has published a white paper detailing the analysis of longitudinal, real-world data (RWD) generated from patients using HOPE® 1.

In November 2020 Zelira entered into an agreement with Emyria Ltd to conduct an observational trial for patients diagnosed with ASD treated with Zelira's HOPE® 1 product. Under the study agreement, Emyria provided to Zelira longitudinal RWD collected from ASD patients prescribed a HOPE® product. Data included efficacy and safety measures and analysis related to comorbidities, concomitant medications, and dosing information.

The longitudinal, real-world data (RWD) of 45 patients was generated from two data sources: 1) dispensing data obtained as part of Zelira's regulatory obligations and 2) Zelira sponsored observational trial conducted by Emyria's Emerald Clinics (n = 19).

The results published in a white paper are available on Zelira's website here.

A summary of the key findings include:

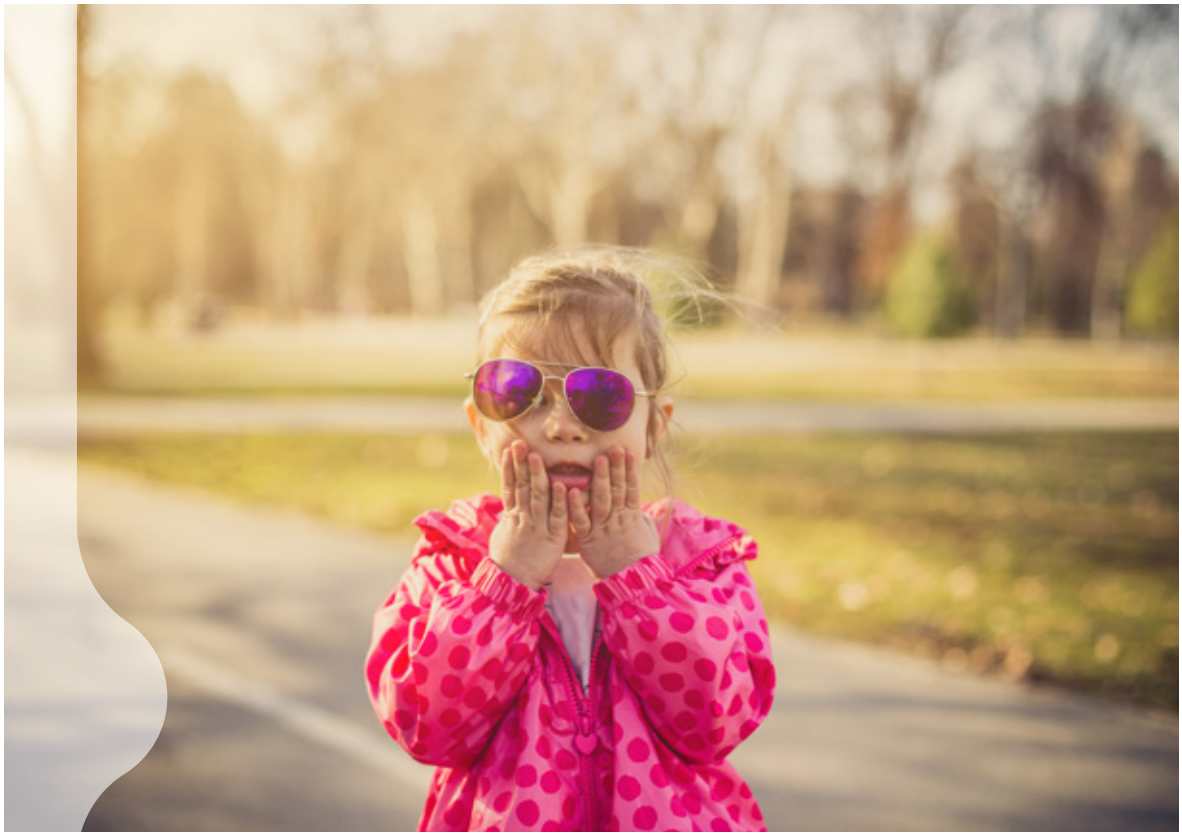
- Mean age of patients on HOPE® 1 was 14.1 years of range; the youngest patient was 5.1 years.
- Mean time on treatment was 4.8 months; maximum treatment time to-date was 8.9 months
- HOPE® 1 appears safe:
  - A total of 25 adverse events occurred in 9 individuals. No serious adverse events were observed. All adverse events were mild and transient.
  - Some patients were on concomitant medications which included anti-psychotics, and selective serotonin reuptake inhibitors
- HOPE® 1 appears to be effective:
  - As the time patients spent on HOPE® 1 increased, so too on average did the clinicians rating of CGI Improvement and CGI Efficacy; close to 70% of patients were rated by clinicians as having achieved a moderate therapeutic effect after 5 months on HOPE® 1.
- The average effective daily dose of HOPE® 1 for patients 16 years and under was 2.5mL (equating to 12.5mg THC: 12.5mg CBD per day) and 3.6 mL (equating to 17.9mg THC: 17.9mg CBD per day) for patients over the age of 18.

Zelira's proprietary HOPE® 1 formulation was launched in Australia in October 2020 and is available to prescribers and patients through the Therapeutic Goods Administrations (TGA) Special Access and Authorised Prescriber Schemes.

Zelira Therapeutics Managing Director, Dr Oludare Odumosu commented:

"Physicians and patients often ask for proof of the safety, efficacy, and dosing guidelines for cannabinoid-based medicines. Zelira is pleased to share the results from this longitudinal real-world trial because it provides prescribers with empirical information and additional confidence to prescribe HOPE® 1.

These results provide additional clinical and regulatory validation for our products as we expand into highly regulated global markets."



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

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About Zelira www.zeliratx.com

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) is a leading global biopharmaceutical company in the research, development and commercialisation of cannabinoid-based medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to access the world's largest and fastest growing markets. The Company is focused on developing and clinically validating branded cannabinoid-based medicines for the treatment of a variety of medical conditions in its Rx business, including insomnia, autism and chronic non-cancer pain.

The Company has two proprietary formulations under the HOPE® brand that are generating revenues in Australia, Pennsylvania, Louisiana and Washington D.C. with other states in the US expected to follow. Zelira is also generating revenue in Australia from its proprietary and patented Zenivol® - a leading cannabinoid-based medicine for treatment of chronic insomnia. Zenivol® has successfully completed the first Phase 1b clinical trial for chronic insomnia where it was found to be a safe and effective treatment. This clinical trial is published in the prestigious journal 'Sleep'. In 2020, Zelira partnered with SprinJene®®Natural to develop and commercialise natural and organic oral care products under the SprinjeneCBD brand, as part of Zelira's OTC business. The SprinjeneCBD toothpaste product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids and based on the proprietary and patented technology of Blackseed oil and Zinc, that will be launched by Zelira's Oral Care OTC business.

Zelira 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.