

Emyria engages Calvert Labs for preclinical CBD studies on novel synthetic cannabinoid platform

Highlights:

- Emyria has signed a Master Services Agreement (MSA) with leading North American preclinical contract research organisation (CRO), Calvert Labs, an Altasciences Company in support of Emyria's TGA and FDA registration programs
- Calvert Labs, an Altasciences Company, has a proven track record of performing FDA-approved studies across a broad range of therapeutic indications and specialises in the design, conduct and interpretation of discovery efficacy pharmacology and GLP toxicology studies
- The MSA engages Calvert Labs, an Altasciences Company, to conduct a range of preclinical and animal pharmacokinetic, bioavailability and toxicology studies to help rapidly optimise Emyria's novel, synthetic cannabinoid drug platform with the complement bioanalysis being conducted at Altascience Company Inc, in Laval, Quebec
- The first study is expected to commence in October, and will assist Emyria in finalising dose formulation prior to commencing EMD-003 pivotal trials

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development and care delivery company, has engaged Calvert Labs, an Altasciences Company, to design and conduct a range of preclinical drug development and optimisation programs related to Emyria's proprietary, synthetic cannabinoid drug development programs targeting registration with the TGA and FDA. *(See ASX announcement 13 August 2021)*

Under the MSA, Calvert Labs, an Altasciences Company, will focus on generating preliminary toxicology and pharmacokinetics data enabling the human clinical trials for Emyria's proprietary, synthetic cannabinoid platform.

These studies will help optimise the final dose form for Emyria's lead program, EMD-003 - targeting registration with the TGA as well as support additional drug development programs pursuing registration with the FDA and other global regulators.

Emyria's Managing Director, Dr. Michael Winlo, said: "We are delighted to be working closely with Calvert Labs, an Altasciences Company and world-class preclinical CRO.

This preclinical work will help strengthen Emyria's intellectual property relating to our synthetic cannabinoid platform. Importantly, this work will help guide the novel formulation, delivery, and dosing strategies of our platform as we prepare our drug development programs for pivotal clinical trials"



Calvert Labs, an Altasciences Company

Calvert Labs, an Altasciences Company, has a proven track record of performing FDA-approved studies across a broad range of therapeutic indications.

Notably, Calvert Labs, an Altasciences Company, has extensive experience in neurological and psychological diseases and has a large pool of neuropsychopharmacology models to assist in the conduct of complex neuropsychological drug development. They have also helped companies with complex drug development for pain and gastrointestinal diseases.

Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customisable to specific sponsor requirements.

Emyria's EMD-003 is Emyria's first drug registration program targeting the symptoms of psychological distress. EMD-003 is aiming to be a Schedule 3, over-the-counter, low-dose pure cannabidiol drug and will be the first to make use of Emyria's proprietary, synthetic dose form. *(See ASX releases 07 Apr 21 and 13 August 2021).*

This announcement has been approved and authorised for release by the Managing Director of Emyria Limited.

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About Emyria (www.emyria.com)

Emyria Limited is a clinical drug development and care delivery company. **Emyria's Treatments** target large unmet needs and are focused on obtaining approval ("registration") with major global regulators. Emyria's treatment development programs are informed by insights generated from extensive analysis of **Emyria Data** - deep, ethically-sourced clinical evidence that is gathered with patients across Emyria's independent clinical services (**Emerald Clinics** - www.emeraldclinics.com.au)

Emyria Data provides deep treatment insights and is therefore a source of unique IP, strategically designed drug development and personalised care programs.

About Altasciences (www.altasciences.com)

Altasciences is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.

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.