ASX Announcement

13 Apr 2022

emyria
myriad data.
individual care.

Clinitrials to lead multi-site Phase 3 trial for EMD-RX5

Highlights:

- Emyria has entered into a **Masters Services Agreement** (MSA) with leading Australian and New Zealand clinical site management organisation, Clinitrials
- Clinitrials to coordinate the pivotal Phase 3 clinical trial of EMD-RX5, Emyria's first proprietary, ultra-pure cannabinoid medicine and on-track to commence following the successful completion of the Phase 1 study currently underway
- EMD-RX5 is initially targeting registration as an over-the-counter (Schedule 3) treatment for the symptoms of psychological distress which affects 15% of the adult population and for which there is currently no over-the-counter treatment [1]

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotechnology company leveraging real-world patient data to develop treatments for unmet needs, is pleased to announce it has entered into a Masters Service Agreement (MSA) with leading Australian Contract Research Organisation, Clinitrials.

Under the MSA, Clinitrials will lead the preparation, ethics submission, patient recruitment and conduct of Emyria's pivotal Phase 3 clinical trial at 5-6 sites across Australia. The Phase 3 trial is expected to support the registration of EMD-RX5 with the TGA as an over-the-counter treatment for the symptoms of psychological distress.

Clinitrials were founded 3 years ago and have already successfully conducted 15 clinical trials and now operates a unique model as both a Contract Research Organisation (CRO) and Site Management Organisation (SMO).

Emyria's wholly-owned clinical service subsidiary, already operating across Australia, is expected to further accelerate recruitment by helping identify suitable patients who will be referred for formal screening at independent sites managed by Clinitrials.

The MSA also allows Clinitrials and Emyria to rapidly commence additional clinical trials to support Emyria's growing drug registration programs comprising ultra-pure cannabinoid-based medicines and novel MDMA analogues.

The pivotal Phase 3 trial for EMD-RX5 is expected to commence immediately following the successful completion of the Phase 1 study currently in progress.

Key terms of the MSA are as follows:

Scope: This Agreement formalises activities between Emyria and Clinitrials with respect to the conduct of clinical trials by Clinitrials on behalf of Emyria.

Other Key Provisions: All intellectual property rights in any background IP remain with the party that contributed the background IP. All intellectual property rights in the services IP vest with Emyria.

Term and Termination: Agreement commencement date: 12 April 2022, Agreement expiry date: 12 April 2024. Emyria may extend the Agreement by notice in writing. Either party may terminate the Agreement with 30 days written notice. Either party may terminate the Agreement with written notice to the other party 14 days following the other party's failure to remedy a breach of the Agreement.

Fees: Clinitrials fees under the Agreement are based on specific clinical trial activities as defined in separate Work Orders. Total fees will be invoiced for work performed on a monthly basis.

Emyria's Managing Director, Dr. Michael Winlo said: *"Clinitrials have developed a reputation for rapid patient recruitment via the deep relationships they have established with multiple general and specialist medical practices around Australia.*

We are very pleased to be working closely with Clinitrials to deliver a pivotal Phase 3 clinical trial in support of the registration of Emyria's first proprietary and ultra-pure cannabinoid capsule, EMD-RX5. EMD-RX5 is targeting registration for the treatment of the symptoms of psychological distress - a condition affecting 15% of adults and for which there is currently no approved over-the-counter treatment.

EMD-RX5 is currently completing a Phase 1 clinical trial comparing the relative bioavailability of our first ultra-pure cannabinoid formulation to the sole registered and reimbursed CBD oil in the global market to date, Epidyolex.

We believe EMD-RX5, and our second proprietary CBD dose form - EMD-RX7 - have the potential to become registered treatments for multiple indications and I look forward to providing further updates on our registration progress as well as our growing cannabinoid and MDMA analogue pipeline in the near-term."

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

For further information:

Dr. Michael Winlo
Managing Director
+61 (0) 8 6559 2800
mwinlo@emyria.com

Lexi O'Halloran
Media/Investor Relations
+61 (0) 404 577 076
investors@emyria.com

Andrew Williams
Media Relations
+61 (0) 412 614 125
awilliams@emyria.com

References:

[1] Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221. Canberra: AIHW.

About Emyria (www.emyria.com)

Emyria Limited develops biopharmaceuticals guided by proprietary Real-World Data collected with patients across its wholly-owned clinical service subsidiary, Emerald Clinics.

Emyria's current clinical development programs are focussed on the registration of proprietary formulations of cannabinoid-based medical treatments (CBMTs) and novel MDMA ('ecstasy') analogues with major global regulators. Emyria's programs target major unmet needs such as mental health disorders and chronic pain.

Emyria's Real World Data (RWD) guides each of Emyria's clinical development programs and care models. Emyria RWD is deep, ethically-sourced clinical evidence gathered with thousands of patients who also receive personalised care at Emerald Clinics.

Emyria is therefore uniquely providing care to patients, generating clinical evidence and advancing multiple proprietary treatment programs towards registration.

About Clinitrials (www.clinitrials.com.au)

Clinitrials is a leading Contract Research Organisation (CRO) and Site Management Organisation (SMO) partnering with Sponsors, investigators, sites and participants to facilitate the successful delivery of clinical trials across Australia and New Zealand with the goal of improving health care outcomes for patients.

Clinitrials was founded in 2019 and is headquartered in Perth, Western Australia.

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.