ASX Announcement

04 Aug 2022

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Preclinical studies initiated for MDMA-inspired analogues

Highlights:

- Institute of Respiratory Health (IRH) engaged to conduct human cell-line studies and help advance Emyria's MDMA-inspired drug discovery partnership with the University of Western Australia (UWA)
- IRH's preclinical program will evaluate a set of unique MDMA-inspired analogues suggested to have "anti-fibrosis" effects, but limited neuropsychiatric action, based on early screening results
- Approval received from the US Drug Enforcement Agency (DEA) to transport 5 high priority MDMA-analogues to the USA, allowing for engagement with leading US-based research bodies and potential partners
- Emyria and UWA continue expanding one of the world's largest libraries of novel MDMA-inspired analogues

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech, is pleased to announce the initiation of human cell-line preclinical studies to advance its MDMA-inspired drug discovery partnership with the University of Western Australia.

MDMA ('ecstasy') is showing promise as an adjunct to psychotherapy for the treatment of major unmet mental health needs (i.e "psychedelic-assisted therapy").

Emyria aims to develop new analogues inspired by MDMA. Like MDMA, its analogues are small, orally absorbed and central-nervous penetrating molecules that interact with a variety of targets in the brain and peripheral tissues and therefore hold promise as new treatments for a range of neurological and non-neurological disorders.

Emyria has created and screened over 125 MDMA-inspired analogues led by Professor Matt Piggott in partnership with the University of Western Australia. Prof. Piggott is an expert in medicinal chemistry and an international leader in modifying MDMA to create novel analogues with therapeutic potential. *(See ASX release 05 Aug 2021)*

Based on initial screening, Emyria has identified three potential therapeutic areas for its MDMA-inspired drug discovery program:

1. **treatments for major mental health disorders** where more potent and shorter-acting MDMA-like treatments, when given alongside psychological therapy, may offer advantages over standard MDMA in drug-assisted therapy
2. **treatments for neurological disorders** where selective neurological receptor effects are desired and;
3. **treatments for non-neurological disorders** where selective activity at peripheral (non-brain) targets are of interest

Preclinical studies are now commencing for leading drug candidates in each therapeutic area. The first preclinical program will explore the antifibrotic potential of a priority set of novel MDMA analogues.

Some compounds structurally related to MDMA are known to increase the risk of developing heart valvulopathy (a fibrotic disorder). As a result, initial safety tests are conducted on each new MDMA-like analogue in order to screen out compounds that pose the greatest risk of inducing fibrosis. However, these same screens can also identify novel compounds with the potential to address or, possibly reverse, fibrosis.

Initial screening of the MDMA analogue library identified a number of novel compounds with potential anti-fibrotic activity. To evaluate the therapeutic potential of these compounds further Emyria has engaged the Institute of Respiratory Health (IRH) in Western Australia to conduct a series of human cell line assays under the leadership of Associate Professors Steven Mutsaers and Cecilia Prêle. These assays will evaluate the ability of the new compounds to inhibit "fibroblast to myofibroblast" differentiation and collagen deposition in normal human lung fibroblast cell lines. These assays may reveal potential to treat diseases involving fibrosis, the thickening or scarring of tissue. Initial results are expected 2 months from study commencement and the project will be funded from the payments already provided to UWA.

Emyria's Managing Director, Dr. Michael Winlo said: *"We are delighted to commence this preclinical program with the IRH, a leading translational research group, to examine the anti-fibrosis potential of some of our unique MDMA analogues.*

Fibrotic diseases represent a major group of unmet medical needs and our early screening results indicate some analogues may have potent antifibrotic activity.

Emyria's New Drug Discovery Program inspired by MDMA continues to grow via our partnership with the University of Western Australia. We now have three clear therapeutic focus areas - fibrotic diseases, next-generation MDMA for drug-assisted therapy and treatments for other neurological conditions - and I look forward to updating the market on each preclinical program as it advances."

Emyria also received notice from the US Drug Enforcement Agency (DEA) that a set of 5 high priority compounds can be imported into the US. DEA approval is the first key step to initiating work with US-based research institutions and partners who are exploring the use of psychedelic-assisted therapies as innovative medical treatments. Subsequent to the DEA approval, the team at UWA have begun scaling up the synthesis of the 5 selected compounds to support further studies.

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

For further information:

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

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

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

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UPCOMING DRUG DEVELOPMENT MILESTONES

CLINICAL PROGRAMS
Repurposing "ultra-pure" cannabinoids

PRE-CLINICAL PROGRAM

EMD-RX5 *"direct-to-consumer"* program	**EMD-RX7** *"prescription medicine"* program	**MDMA**-inspired drug development
Formulation optimisation ✓	**Formulation optimisation** ✓	**Screening results** for first 85 compounds ✓
Phase 1 ✓	**Phase 1**	**First patent family** filed ✓
Ethics submitted for Phase 3 ✓	Pre-IND **(FDA)**	Batch **3** sent ✓
Phase 3 commencement	**Pivotal** trials	Batch 3 **screening results**
Regulatory submission		**Create and screen** additional batches
Commercial strategy **Australia**		**Metabolic** studies ✓
Commercial strategy **Europe**		**Preclinical assays** *(multiple animal models)*
Commercial strategy **USA**		**Human cell** line assays ✓
		Lead selection
		Phase 1 trials

ABOUT EMYRIA | emyria.com

Emyria Limited is a clinical stage biotech focussed on accelerating treatment development and improving patient care by:

1. **Collecting and analysing Real-World Data (RWD):** Emyria gathers ethically-sourced clinical evidence with patients across Emyria's independent clinical services *(emeraldclinics.com.au)*. Emyria's proprietary RWD provides deep treatment and drug development insights.
2. **Repurposing promising treatments:** Emyria uses its RWD to improve the formulations of, and find new indications for, select medications. Emyria's first repurposed and proprietary drug products (EMD-RX5 and EMD-RX7) incorporate Ultra-Pure cannabinoids and are targeting global registration opportunities as over-the-counter and prescription-only medicines.
3. **Developing analogues of promising new compounds**: Emyria collaborates with leading institutions to develop new chemical entities inspired by promising molecules. Emyria's first new chemical entity program is focussed on generating novel MDMA analogues with the potential to become registered therapies for a range of major unmet needs.

ABOUT THE INSTITUTE FOR RESPIRATORY HEALTH | resphealth.com.au

The Institute for Respiratory Health has been researching lung conditions for 20 years. The IRH is one of two institutes in the whole of Australia looking after the nation's lungs. The IRH:

- Conducts and fosters innovative basic and clinical research to prevent, and better understand respiratory conditions and improve their diagnosis and management.
- Translates their research into improved treatments for people with lung disease.
- Campaign in Western Australia for an increased awareness of and investment in respiratory education and research.

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.