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**Delivering & developing new treatments for mental health & neurological conditions**

**ASX Announcement** | 20 June 2024

# Empax Centre Selected as Key Trial Site for Transcend Therapeutics' New PTSD Treatment Study

## HIGHLIGHTS

Emyria's newly opened Empax Centre selected for "IMPACT-2" trial on PTSD, emphasising its advanced research capabilities and infrastructure

The trial aims to investigate the effects of methylone on neuroplasticity and PTSD symptoms, leveraging Emyria's clinical expertise in psychological trauma care

For participants enrolled at Empax Center, Emyria will earn fees at market rates for specialist work performed

The trial's integration with Emyria's clinical services exemplifies the Company's commitment to maximise the potential of its unique facilities and capabilities

**Emyria Limited (ASX: EMD)** ("Emyria", or the "Company") focused on developing innovative treatments for mental health and neurological conditions, is pleased to announce its newly inaugurated Empax Centre has been selected as a key site for a clinical trial sponsored by New York-based Transcend Therapeutics. The trial will evaluate the safety and efficacy of methylone, a novel rapid-acting neuroplastogen known for promoting new nerve cell growth in areas affected by PTSD, depression, and anxiety.

Emyria's Empax Centre [1] is a state-of-the-art facility dedicated to the delivery and evaluation of new treatments for mental health. The Empax Centre provides critical infrastructure for the safe administration and evaluation of new medications in both clinical trial and Real-World settings and embodies Emyria's mission to deliver and develop new treatments that significantly improve patient outcomes.

Emyria will receive compensation for facilitating the trial, highlighting its value and expertise in psychological trauma care and clinical trial delivery. This recognition underscores Emyria's leadership in mental health innovation.

Methylone, identified as TSND-201 by Transcend Therapeutics, is a novel MDMA analogue which has shown promise in rapidly activating neuroplasticity gene expression, including BDNF [2, 3, 4], which is crucial for the recovery processes in neuropsychiatric disorders.

The Phase 2 trial, titled: An Evaluation of the Safety and Efficacy of Methylone for the Treatment of PTSD, also referred to as "IMPACT-2" (Investigation of Methylone for Post-Traumatic Stress Disorder [PTSD]) will run in two parts with plans to enroll up to 79 participants across multiple sites in Australia and United States. For participants enrolled at Empax Center, Emyria will earn fees at market rates for specialist work performed.

**Dr. Michael Winlo, CEO:** *"We are delighted to work with Transcend Therapeutics on this exciting trial that highlights our dedication to bringing new treatments to our patients while utilising the full capabilities of our Empax Centre.*

*Site selection is international recognition of our team's unique capabilities and we look forward to working with Transcend Therapeutics and our network of specialists to advance this trial and improve mental health outcomes for patients with severe PTSD."*

The parties have entered into a standard form clinical trial research agreement, which is binding and provides industry standard termination provisions. There are no material conditions precedent under the agreement. If the trial proceeds as planned, Emyria expects to competitively recruit at least 20 participants and will provide comprehensive specialist mental health services including initial screenings, ongoing safety and efficacy assessments, precise dosing, patient monitoring and data entry — tasks that require the expertise of trained psychiatrists and therapists. Each participant will receive a level of care reflecting the depth and rigour of these services, with fees structured to align with market rates for such specialised work.[5]

**IMPACT-2 trial details** (*clinicaltrials.gov identifier* **NCT06215261**)**:**

| ITEM | DESCRIPTION |
|---|---|
| **Protocol Title** | An Evaluation of the Safety and Efficacy of Methylone for the Treatment of PTSD |
| **Primary Endpoint(s)** | Evaluate the safety and efficacy of three doses of methylone, with each dose separated by 1 week, in participants with PTSD. |
| **Development Phase** | Phase 2 |
| **Expected Duration & Enrollment Target** | A two-part study. Part A is an open-label assessment in up to 15 participants with PTSD; Part B is a randomised (1:1), double-blind, placebo-controlled assessment in up to 64 participants.<br>After completion of Part A, enrolment for Part B will begin.<br>Empax Centre will recruit competitively for Part A and Part B. |
| **Selection Criteria** | Participants will be adults (age 18 to 70, inclusive) who meet the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for current PTSD, with a symptom duration of at least 6 months at screening. Eligible participants will have severe PTSD symptoms (based on a Clinician-Administered PTSD Scale for DSM-5 [CAPS-5] total severity score of ≥35 at Screening). |
| **Trial Locations** | The trial will take place at Emyria's Empax Centre and other sites around Australia and the United States. |
| **Trial Standards** | The study is being conducted in accordance with international best practice standards and fully complies with the principles of Good Clinical Practice (**GCP**), as outlined by the International Council for Harmonisation (**ICH**). |

**EMYRIA'S INTERACTIVE INVESTOR HUB**
**Investorhub.emyria.com** Interact with Emyria's announcements and updates by asking questions and comments, which our team can respond to where possible.

**About Transcend Therapeutics: (www.transcendtherapeutics.com)**
Transcend Therapeutics is a clinical-stage, neuroscience-focused company committed to developing rapid-acting treatments for neuropsychiatric diseases. With a mission to address the unmet needs of millions who have not found relief in existing psychiatric medicines, Transcend is advancing TSND-201 (methylone) as a robust solution for PTSD, Major Depressive Disorder (MDD), and other central nervous system conditions. As a Public Benefit Corporation, Transcend dedicates 10% of its founding shares to nonprofits supporting scientific research and increasing access to mental health solutions.

**References:**


1. See ASX release 10 April 2024
2. Warner-Schmidt et al., American Society for Clinical Psychopharmacology annual meeting, 2023.
3. Kredlow et al., Neuropsychopharmacology, 2021.
4. Liu et al., Nature Communications, 2020.
5. Emyria bills its specialised professional services at competitive market rates of between $150 to $600 per hour, with each trial participant requiring an estimated 30 to 50 hours of service throughout the duration of the study.


This release has been approved by the Board of Emyria.

***For further information, investment opportunities, or more about our approach to mental health treatment, please contact:***


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