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American firm Enveric Biosciences opens Australian subsidiary to work on anxiety disorder

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First-in-human clinical trial investigating Enveric's lead product candidate, EB-373 targeting anxiety disorder expected to initiate in the fourth quarter of 2023

Enveric Biosciences, a US-based biotechnology company dedicated to the development of novel small-molecule therapeutics for the treatment of anxiety, depression, and addiction disorders, has established Enveric Therapeutics, an Australia-based subsidiary, to support the company's plans to advance its EVM201 Series, including lead candidate EB-373, towards the clinic.

Enveric Therapeutics will oversee the company's preclinical, clinical, and regulatory activities in Australia, including ongoing interactions with the local Human Research Ethics Committees (HREC) and the Therapeutic Goods Administration (TGA), Australia's regulatory authority.

The company's lead drug candidate, EB-373, is a next-generation synthetic New Chemical Entity (NCE) designed as a psilocin prodrug and developed leveraging its Psybrary drug discovery platform. Enveric expects to initiate a Phase 1 first-in-human clinical trial investigating EB-373 targeting anxiety disorders in the fourth quarter of 2023.

Australia has enacted several policies designed to enable more efficient and cost-effective early-stage product development. Clinical trials conducted under the Clinical Trial Notification (CTN) Scheme or Clinical Trial Exemption (CTX) Scheme – the two pathways endorsed by the TGA for administering clinical trials in Australia – do not require an active Investigational New Drug (IND) application to proceed. Further, The Australian Government's Research and Development Tax Incentive provides a 43.5 percent rebate for every dollar spent on R&D. Additionally, Australian regulators have recently advanced guidance intended to encourage the development of psychedelic-derived prescription therapeutics.