



## U.S. FDA Grants Reunion Neuroscience's Luvesilocin (RE104) Breakthrough Therapy Designation Status

*-- Breakthrough Therapy Designation Based on Positive RECONNECT Phase 2 Clinical Data --  
-- Aligned with U.S. Food and Drug Administration on Registrational Path for Luvesilocin in Postpartum Depression (PPD); On Track to Initiate Phase 3 Trial in 2026 --*

**MORRISTOWN, New Jersey, February 23, 2026** – Reunion Neuroscience, Inc., a clinical-stage biopharmaceutical company committed to revolutionizing the treatment of underserved mental health disorders through the advancement of next-generation psychedelic-inspired therapeutic solutions, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) to luvesilocin (formerly RE104) for the treatment of postpartum depression (PPD).

BTD for luvesilocin is supported by strong positive efficacy data from the RECONNECT Phase 2 clinical trial. The study met its primary endpoint, demonstrating a statistically significant and clinically meaningful reduction in Montgomery-Åsberg Depression Rating Scale (MADRS) total score on Day 7 ( $p=0.0094$ ). Additionally, treatment with luvesilocin delivered rapid and durable efficacy starting as early as Day 1 and continuing through Day 28, with substantial and clinically meaningful improvements across key measures of mood and anxiety. Furthermore, 70% of patients receiving luvesilocin 30mg were in remission at both Day 7 and Day 28. [Topline data](#) were announced in August 2025, and [full results](#) were presented at the American College of Neuropsychopharmacology (ACNP) Annual Meeting in January 2026.

The FDA's BTD is designed to expedite the development and review of drugs that are intended to treat a serious or life-threatening condition, and for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy. BTD provides eligibility for all Fast Track designation features, along with enhanced FDA guidance on development and increased engagement with senior FDA leadership.

"For far too long, mothers living with PPD have had limited treatment options, none of which consistently offer rapid, durable relief during one of the most critical periods of their lives. Receiving FDA Breakthrough Therapy Designation for luvesilocin underscores both the urgency of this unmet need and the promise of our clinical data to date relative to current available treatment options," said Mark Pollack, M.D., Chief Medical Officer of Reunion. "We are deeply encouraged by what this milestone represents, not only for our PPD program, but for the growing validation of psychedelic-inspired medicines as potentially transformative treatments for depression and anxiety disorders. We look forward to advancing luvesilocin as quickly as possible for the mothers and families who need better options."

### **About Luvesilocin**

Luvesilocin is a proprietary, potential best-in-class, patented prodrug of 4-OH-DiPT, which is administered via a subcutaneous injection. Reunion designed luvesilocin to deliver rapid efficacy with a short psychoactive experience, making luvesilocin more convenient than the longer experience and monitoring required with traditional psychedelics like psilocybin or LSD.

Reunion is evaluating luvesilocin as a subcutaneous administration for the treatment of mood and anxiety disorders. The Company expects to initiate a pivotal Phase 3 clinical trial in PPD in 2026 which, if successful, could support potential registration of luvesilocin. Additionally, Reunion is enrolling patients in the Phase 2 REKINDLE ([NCT07002034](#)) clinical trial in patients with adjustment disorder related to cancer and other medical illnesses, and plans to commence the Phase 2 RECLAIM clinical trial in generalized anxiety disorder in the first quarter of 2026.

### **About Reunion Neuroscience, Inc.**



Reunion Neuroscience is a clinical-stage biopharmaceutical company committed to revolutionizing the treatment of underserved mental health disorders through the advancement of next-generation psychedelic-inspired therapeutic solutions. Reunion is actively investigating the use of its lead product candidate, luvesilocin, in postpartum depression, adjustment disorder and generalized anxiety disorder and may in the future expand to additional neuropsychiatric indications where there remains a significant unmet need that is not addressed by the current standard of care. Reunion has advanced a lead candidate, RE245, from its non-psychedelic discovery program and plans to file an IND in 2026. To learn more, visit <https://reunionneuro.com>, and follow Reunion on [LinkedIn](#) and [Bluesky](#).

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