Reunion Neuroscience Presents Full Data from RECONNECT Phase 2 Clinical Trial of RE104 for the Treatment of Postpartum Depression (PPD) at ACNP Annual Meeting

-- Met Primary Endpoint with 30mg Dose of RE104 with 23.0-Point Total Score Reduction in Montgomery-Åsberg Depression Rating Scale (MADRS) on Day 7 (p=0.0094) --
-- Demonstrated Rapid and Durable Efficacy Starting as Early as Day 1 and Continuing Through Day 28, with Substantial and Clinically Significant Improvements Across Key Measures of Mood and Anxiety --
-- Aligned with U.S. Food and Drug Administration (FDA) on Registrational Path for RE104 in PPD; On Track to Initiate Phase 3 Trial in 2026 --

MORRISTOWN, New Jersey, January 20, 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 the full results of RECONNECT, a Phase 2 clinical trial evaluating RE104 in adult female patients with moderate-to-severe PPD. The data were presented at the American College of Neuropsychopharmacology (ACNP) Annual Meeting and the poster presentation is now available on the Reunion website – please click here to access the poster presentation: RE104: A Novel Serotonergic Psychedelic 4-OH-DiPT Prodrug for the Treatment of Postpartum Depression.

RECONNECT met its primary endpoint, with a statistically significant and clinically meaningful reduction in MADRS total score observed on Day 7; clinically meaningful reductions in MADRS were observed for RE104 30mg-treated patients on the first day following administration and maintained through the 28-day follow-up. Substantial and clinically meaningful improvements in other key secondary endpoints, including MADRS response and remission rates and other measures of PPD symptoms, were also observed.

With these data in-hand, the Company recently completed an End of Phase 2 meeting with the FDA and expects to advance RE104 into a pivotal Phase 3 trial in 2026. Based on feedback from the FDA, Reunion expects that the results from a single Phase 3 trial, if successful, would complete the data package required to support potential registration of RE104.

“We are encouraged by the data presented today from our RECONNECT study, which underscore RE104’s potential as a new standard-of-care for PPD,” said Mark Pollack, M.D., Chief Medical Officer of Reunion. “These data demonstrate the totality of RE104’s rapid and durable impact – across a range of physician- and patient-reported outcomes and measures of depression, anxiety and well-being. Together, these data highlight the ability of a single dose of RE104 to deliver a rapid, sustained benefit, potentially changing the course of a disease that can otherwise have significant negative impacts on mothers and their babies. We look forward to advancing into a pivotal Phase 3 trial this year, as we work to deliver a much-needed option to women facing the serious complications of PPD.”

Full Data from the Phase 2 RECONNECT Clinical Trial of RE104
RECONNECT (NCT06342310) was designed as a multi-center, randomized, double-blind, parallel-group, active dose-controlled clinical trial to evaluate the safety and efficacy of a single 30mg subcutaneous dose of RE104. The trial enrolled 84 adult female patients with moderate-to-severe PPD (defined as a Hamilton Depression Rating Scale (HAMD-17) ≥24), randomized to receive RE104 30mg or a subperceptual dose of 1.5mg.

Patient demographics and baseline characteristics were generally similar between the two groups; patients in the 30mg group presented with an average MADRS total score of 33.4 and 7.64 months duration of disease, and patients in the 1.5mg group presented with an average MADRS score of 33.2 and 7.02 months duration of disease. There were more patients in the 30mg group on concurrent treatment (SSRI, therapy or both) at baseline (31.7% versus 14.0%).

The primary endpoint was the change from baseline at Day 7 in total MADRS score, a 10-item clinician-rated scale measuring depression severity. Key secondary endpoints included in today’s data presentation include the change in MADRS at other timepoints, response rates (≥ 50% MADRS reduction), remission rates (MADRS ≤ 10), change in Hamilton Anxiety Rating Scale (HAM-A), Clinical Global Impression – Improvement (CGI-I), and Barkin Index of

Maternal Function (BIMF), as well as overall safety and tolerability. Click here to view the data presented in the poster presentation.

Clinical Development Plans for RE104
Reunion plans to initiate a pivotal Phase 3 trial of RE104 for the treatment of PPD in 2026. The PPD program is part of a broader effort to evaluate RE104 as a single subcutaneous administration for the treatment of mood and anxiety disorders. The Company 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 RE104
RE104 is a proprietary, potential best-in-class, patented prodrug of 4-OH-DiPT, which is administered via a single subcutaneous injection. Reunion designed RE104 to deliver a short, acute psychoactive experience compared to longer experience duration with psychedelics like psilocybin or LSD.

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, RE104, 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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