

**Reunion Neuroscience Announces Publication of RE104 Phase 1 Data in The Journal of Clinical Psychopharmacology**

-- Phase 1 Data Highlight RE104 Favorable Safety Profile and Short Duration Psychoactive Experience --

-- Topline Results from RECONNECT Phase 2 Trial of RE104 in Postpartum Depression (PPD) Anticipated in Q3 2025 --

**MORRISTOWN, New Jersey, July 22, 2025** – 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 publication of a manuscript entitled “Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Subcutaneous RE104: A Double-Blind, Randomized, Single Ascending Dose Placebo-Controlled Study,” describing the results of a Phase 1 study of RE104 in the peer-reviewed *Journal of Clinical Psychopharmacology*. The publication is available online and can be found [here](#).

In this Phase 1 study, a single subcutaneous dose of 5mg up to 40mg RE104 was administered to healthy adult volunteers. Acute psychoactive experiences were observed with doses greater than 5mg, which lasted 3-4 hours on average. All doses presented a favorable safety and tolerability profile with effects similar to those reported with psilocybin. Reunion Neuroscience is currently evaluating RE104 in the RECONNECT Phase 2 trial in adult female patients with moderate-to-severe postpartum depression (PPD). Topline data from the study are expected in the third quarter of 2025.

“The publication of the Phase 1 data in a leading peer-reviewed scientific journal demonstrates the recognition of RE104’s potential as a differentiated psychedelic therapy,” said Greg Mayes, Chief Executive Officer of Reunion Neuroscience. “Findings from this study highlight RE104’s favorable safety and tolerability profile, as well as the ability to dose-adjust the intensity of the psychedelic experience to achieve high target engagement suggested by pharmacodynamic measurements. These results provided the foundation for dose selection for our Phase 2 trials of RE104 in both postpartum depression (PPD) and in adjustment disorder (AjD). As we approach the upcoming data readout from our RECONNECT trial later this quarter, we are encouraged by these early findings and reaffirm our belief in RE104’s potential to deliver transformative benefits to patients in need.”

The Phase 1 study was a double-blind, randomized, placebo-controlled study evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of a single subcutaneous dose of RE104 in 48 healthy adult participants. In the study, RE104 was generally safe and well-tolerated up to 40 mg with no serious adverse events or deaths reported. Most observed treatment-emergent adverse events (TEAEs) were found to be mild-to-moderate and occurred acutely under supervision. RE104 was not associated with an increase in suicidality assessed by the Columbia-Suicide Severity Rating Scale (C-SSRS) score and the modified Observer’s Assessment of Alertness and Sedation Scale (MOAA/S) remained largely normal at all timepoints regardless of dose. Following treatment with RE104, the active metabolite, 4-OH-DiPT, was found to appear rapidly in plasma with peak levels correlating with the clinical assessment of drug effect by the modified Drug Effect Questionnaire (DEQ) and Mystical Experience Questionnaire (MEQ) scores. A single subcutaneous injection of 30 mg RE104 was selected as the target therapeutic dose based on a combination of assessments of safety, tolerability and pharmacodynamic effects.

In conjunction with the RECONNECT trial, Reunion also conducted a clinical lactation study in 14 healthy lactating volunteers ([NCT06659263](#)) to characterize the elimination of RE104 and metabolites, as well as any possible transference of drug and metabolites to breastmilk. Results from this study will support a proposal to the FDA for when mothers can safely return to breastfeeding following a single dose of RE104. Final data from this study are expected in the second half of 2025.

The Company also plans to evaluate RE104 in additional neuropsychiatric indications beginning with REKINDLE, a randomized, double-blind, parallel-group, dose-controlled clinical trial evaluating the safety and efficacy of RE104 for the treatment of adjustment disorder (AjD). The Phase 2 study will enroll adult patients with AjD from cancer and other medical illnesses. Reunion expects to initiate REKINDLE in the third quarter of 2025.

#### **About RE104**

The Company's lead product candidate, RE104, is a proprietary, potential best-in-class, patented prodrug of 4-OH-DiPT. Reunion designed RE104 to deliver a short duration psychedelic experience compared to longer duration psychedelics like psilocybin. In a Phase 1 clinical trial, RE104 produced a psychedelic state similar in intensity and quality to psilocybin, but lasting only about half the time (3-4 hours), while demonstrating a similar, favorable safety profile. RE104 is currently being evaluated in the RECONNECT Phase 2 ([NCT06342310](#)) clinical trial, a multicenter, randomized, double-blind, active dose-controlled clinical trial in moderate-to-severe postpartum depression (PPD) patients. Initial data from RECONNECT are expected in the third quarter of 2025. Reunion plans to initiate the REKINDLE Phase 2 clinical trial, a randomized, double-blind, parallel-group, dose-controlled trial in adjustment disorder (AjD) in cancer and other medical illnesses in the third quarter of 2025.

#### **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. In 2023, Reunion became a private company and in 2024, the Company completed Series A financing co-led by MPM BioImpact and Novo Holdings. Reunion is actively investigating the use of its lead product candidate, RE104, in postpartum depression and adjustment disorder, as well as in 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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