Reunion Neuroscience Announces Positive Topline Results from RECONNECT Phase 2 Clinical Trial of RE104 for the Treatment of Postpartum Depression (PPD)

-- Achieved Primary Endpoint with 30mg Dose of RE104 Demonstrating 23.0-Point Reduction from Baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) Score on Day 7, a 5.8-Point Greater Reduction Than Patients Treated with 1.5mg Dose (p=0.0094) --

-- Clinically Meaningful Reductions in MADRS Observed for RE104 30mg on the First Day Following Administration and Maintained Through Day 28 Follow-Up --

-- RE104 Observed to be Generally Well-Tolerated with No Serious Adverse Events; 92.7% of Patients Ready for Discharge Within Four Hours Following RE104 Administration --

-- Preliminary Data from Lactation Study Suggests Mothers Could Return to Breastfeeding Rapidly Following RE104 Treatment --

-- Company Plans to Initiate Pivotal Phase 3 Trial of RE104 in PPD in 2026 --

MORRISTOWN, New Jersey, August 18, 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 positive topline results from its RECONNECT Phase 2 clinical trial evaluating RE104 in adult female patients with moderate-to-severe postpartum depression (PPD). RECONNECT met its primary endpoint with a single 30mg subcutaneous dose of RE104 demonstrating a statistically significant reduction from baseline of 23.0 points in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score on Day 7, as compared to a reduction of 17.2 points in patients treated in the active control arm with a 1.5mg dose of RE104 (difference of 5.80; p=0.0094). Clinically meaningful reductions in MADRS were observed for RE104 30mg on the first day following administration and maintained through the Day 28 follow-up.

77.1% of patients treated with RE104 30mg demonstrated a response to therapy at Day 7, defined as at least a 50% improvement from baseline MADRS total score, as compared to 61.6% of patients who received Active Control. 71.4% of patients treated with RE104 30mg were in remission at Day 7, defined as a total MADRS score of ≤10, as compared to 41.0% of patients who received Active Control. Both response and remission rates were maintained through the Day 28 follow-up. Other key secondary endpoints demonstrated improvements in symptoms that were supportive of the primary endpoint, including the Barkin Index of Maternal Functioning (BIMF) scale, a self-reported measure that assesses overall maternal functioning, providing a holistic view of the patient's well-being and ability to manage life with a new baby.

"PPD remains the most common complication of pregnancy and childbirth in the U.S., affecting approximately 15% of new mothers within the first year after giving birth, with nearly 500,000 women in the U.S. diagnosed annually," said Anita H. Clayton, M.D., Wilford W. Spradlin Professor and Chair of Psychiatry and Neurobehavioral Sciences at the University of Virginia School of Medicine, and lead investigator in the RECONNECT trial. "Despite its prevalence and severity, current treatment options for PPD remain limited and are often slow-acting and burdensome, leaving many new mothers without timely, effective care. Findings from the RECONNECT trial are promising and underscore RE104's potential as a single subcutaneous injection therapy that addresses limitations of current treatments by delivering symptom relief quickly and safely following a single dose of therapy, with minimal disruption to caregiving

responsibilities and a lack of sedation. I look forward to the continued evaluation of RE104 in a Phase 3 trial and believe it could represent a significant shift in the treatment of maternal mental health disorders."

"With PPD, it can seem as if women are watching life from the sidelines, feeling emotionally detached, lacking joy, and unable to bond with their newborns while struggling with guilt and shame that can come with debilitating depression," said Camille Hoffman, M.D., M.Sc., obstetrician-gynecologist, Professor of Maternal Fetal Medicine at the University of Colorado School of Medicine on the University of Colorado Anschutz Medical Campus and investigator in the RECONNECT trial. "Our current treatment options are limited, and we need therapies that help our patients recover rapidly during such a dynamic time of life. The results of the RECONNECT trial are encouraging and provide hope that this therapy may help more mothers overcome the burden of PPD and find their way back to themselves and their families for the moments that matter most."

In RECONNECT, RE104 was observed to be generally well-tolerated, consistent with previously reported Phase 1 safety data with RE104 and other psychedelic agents. The most commonly reported treatment-emergent adverse events were nausea, occurring in 43.9% of patients, and headache, occurring in 34.1% of patients; these adverse events were generally mild to moderate, occurred primarily on the day of treatment, resolved spontaneously, and are consistent with those observed with other agents in the class.

There were no serious treatment-emergent adverse events (SAEs), and no evidence of treatment-emergent suicidal ideation or behavior in either arm. Additionally, there was no evidence of treatment-emergent seizures or serotonin toxicity, and no clinically significant electrocardiogram findings. 92.7% of patients receiving RE104 30mg showed no symptoms or signs that would pose a risk for discharge at the first measure of discharge readiness, taken four hours following treatment. This rapid discharge readiness is consistent with RE104's pharmacology and distinguishes it from other psychedelic agents with similar intensity, such as psilocybin- and LSD- based therapies.

Also today, Reunion announced initial data from its clinical lactation study. Preliminary results from the study suggest that the total amount of metabolites observed in the breastmilk represents less than 0.1% of the 30mg RE104 administered to the mother, an order of magnitude below the level that might potentially cause risk to the infant. While final data from the study will be reviewed by the FDA, Reunion believes these results suggest that mothers who wish to return to breastfeeding following RE104 treatment may be able to do so with limited interruption.

"We are encouraged by the results from our RECONNECT Phase 2 trial, which provide strong clinical validation for RE104 as a well-tolerated and effective treatment for PPD offering rapid relief with minimal interruption to daily activities," said Mark Pollack, M.D., Chief Medical Officer of Reunion. "These data support our proposed plan to advance RE104 into a pivotal Phase 3 trial in 2026."

"We are also evaluating RE104 for the treatment of adjustment disorder (AjD) in cancer and other medical illnesses, and remain on track to initiate the REKINDLE Phase 2 trial in the third quarter of 2025," Dr. Pollack added. "We strongly believe that RE104 has the potential to redefine the standard of care for debilitating disorders such as PPD and AjD, and look forward to realizing its broader application to address a range of underserved mental health conditions."

Clinical Development Plans for RE104
Based on favorable tolerability and efficacy results from RECONNECT, Reunion plans to advance RE104 into a Phase 3 trial for the treatment of PPD. The Company expects to initiate a pivotal Phase 3 trial in 2026.

The RECONNECT trial is part of a broader clinical program studying RE104 as a single subcutaneous administration for treatment of PPD, AjD, and other mental health conditions. The Company expects to initiate the REKINDLE Phase 2 (NCT07002034) trial in patients with adjustment disorder related to cancer and other medical illnesses in the third quarter of 2025, and plans to commence a Phase 2 clinical trial in a third undisclosed significant mental health indication in the first quarter of 2026.

About the RECONNECT Phase 2 Clinical Trial
The RECONNECT Phase 2 clinical trial (NCT06342310) was a multicenter (38 clinical research sites in the U.S.), randomized, double-blind, parallel-group, active dose-controlled clinical trial evaluating 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). Psychotherapy was not provided as part of the RECONNECT trial.

The average age of patients enrolled was 32 (range: 21-45), and the average number of months post-partum was 7.3 (range: 1.5-17.7). Eight patients (9.5%) had prior psychedelic experience (>12 months prior to screening).

About RE104
The Company's lead product candidate, 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. 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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