Reunion Neuroscience Inc. Announces First Patient Dosed in Phase 2 Clinical Trial of RE104 for the Treatment of Postpartum Depression

MORRISTOWN, New Jersey, July 23, 2024 – Reunion Neuroscience Inc., a clinical-stage biopharmaceutical company committed to pushing the boundaries of neuroscience, today announced that the first patient has been dosed in the RECONNECT Phase 2 clinical trial of RE104 for the treatment of postpartum depression (PPD). RE104 was designed to be a safe, fast-acting, single-dose therapy to benefit patients suffering from underserved mental health disorders, including PPD.

"Dosing the first patient in our RECONNECT Phase 2 trial represents an important step forward in our mission of improving the lives of patients and families impacted by PPD," said Greg Mayes, President and Chief Executive Officer of Reunion. "There is a clear need for fast-acting, single-dose treatments with durable efficacy for PPD patients. Reunion is committed to serving not only the unmet need in PPD, but also the broader community affected by mental health disorders through its development programs."

The RECONNECT Phase 2 clinical trial (NCT06342310) is a multicenter, randomized, double-blind, parallel-group, active dose-controlled clinical trial evaluating the safety and efficacy of a single subcutaneous dose of RE104 in adult female patients with moderate-to-severe PPD. The primary endpoint of the trial is the change in total Montgomery-Åsberg Depression Rating Scale (MADRS) score, a 10-item clinician rated scale measuring depression severity from baseline, at Day 7. Key secondary endpoints include the change in total MADRS score from baseline at Day 1, 14 and 28, MADRS response indicating a ≥ 50% reduction in symptoms, MADRS remission with a score of ≤ 10, as well as safety and tolerability.

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. Reunion is actively evaluating the use of RE104 in additional neuropsychiatric indications, including adjustment disorder in cancer patients, where there remains a significant unmet need that is not addressed by the current standard of care.

About Postpartum Depression (PPD)

Postpartum depression (PPD) is one of the most common medical complications during and after pregnancy and is estimated to affect approximately 10-15% of all mothers of

newborns. PPD is a form of major depression that can severely impact women and their families. According to the Centers for Disease Control and Prevention, the leading underlying cause of pregnancy-related death during the first postpartum year are due to mental health conditions, with suicide being the leading manner of death. Women suffering from PPD often experience significant changes in mood, appetite and sleep contributing to feelings of hopelessness, lack of concentration, loss of energy, poor self-esteem and maternal disinterest. We believe there is a significant unmet need for a solution that offers a faster onset of action, greater efficacy after only a single dose, with a fast return to normal daily activities.

About Reunion Neuroscience Inc.
Reunion Neuroscience is committed to pushing the boundaries of neuroscience to develop innovative therapeutic solutions for postpartum depression (PPD) and other underserved mental health disorders. In August of 2023, Reunion Neuroscience became a private company as part of the MPM BioImpact portfolio and in May 2024, the Company completed a $103 million Series A financing co-led by MPM BioImpact and Novo Holdings. Reunion is actively investigating the use of its lead product candidate, RE104, in PPD, as well as in additional neuropsychiatric indications, including adjustment disorder in cancer, where there remains a significant unmet need that is not addressed by the current standard of care. For more information about the company, visit https://reunionneuro.com.

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