Reunion Neuroscience Inc. Announces FDA Clearance of IND Application to Initiate a Phase 2 Study of RE104 for the Treatment of Postpartum Depression

WILMINGTON, September 18, 2023 – Reunion Neuroscience Inc., a clinical-stage biopharmaceutical company committed to developing innovative and patented therapeutic solutions for underserved mental health conditions today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to initiate a Phase 2 study of RE104, a novel serotonergic psychedelic compound, for the treatment of postpartum depression (PPD). The Phase 2 study, the RECONNECT Trial, is a multicenter, randomized, double-blind, parallel-group, active-dose placebo-controlled study, which will evaluate the safety and efficacy of a single subcutaneous dose of RE104 in adult female patients with PPD. The study is expected to begin in Q4 2023 with a targeted data readout in late 2024.

"On the heels of a successful Phase 1 adult healthy volunteer study conducted in Australia earlier this year, authorization from the FDA to initiate our Phase 2 study in the United States later this year is major milestone for patients and the company," said Greg Mayes, Reunion CEO. "Mental health conditions unfortunately remain the leading cause of pregnancy related deaths. There are so few solutions for patients and families suffering from PPD, which has been shown to compromise childhood development and the family unit and can, in the worst cases, lead to serious harm for mother and risk to her child. Reunion is committed to making a significant difference in improving outcomes in this patient population and other mental health disorders."

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 patients in the United States. PPD is a form of major depression that can severely impact women and their families. 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 limited interruption in breast feeding, and a faster return to normal daily activities.

About Reunion Neuroscience Inc.

Reunion is committed to developing innovative therapeutic solutions for underserved mental health conditions. The Company's lead asset, RE104, a proprietary, novel, serotonergic psychedelic compound and the only 4-OH-DiPT prodrug in clinical development, is being investigated as a potential treatment for

postpartum depression that could provide rapid symptom relief and durable efficacy. RE104 is protected under U.S. Patent No. 11,292,765 issued on April 5, 2022 (priority June 30, 2020), with claims for composition of matter, methods of manufacturing, formulations and methods of use for a genus of hemiester tryptamines, including RE104, which could provide protection out to June 30, 2041. Reunion is also developing the RE200 series, which includes preclinical compounds designed with enhanced receptor selectivity to address additional therapeutic applications.

For further information:

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