Reunion Neuroscience Announces First Patient Dosed in REKINDLE Phase 2 Clinical Trial of RE104 for the Treatment of Adjustment Disorder (AjD) in Cancer and Other Medical Illnesses

-- AjD Represents an Area of Significant Unmet Need; No U.S. Food and Drug Administration (FDA)-Approved Therapies Available --

-- Following Positive Topline Data in RECONNECT Phase 2 Trial, Expect to Initiate Phase 3 Trial of RE104 in Postpartum Depression (PPD) in 2026 and RECLAIM Phase 2 Trial in Generalized Anxiety Disorder (GAD) in 1Q 2026--

MORRISTOWN, New Jersey, September 30, 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 dosing of the first patient in REKINDLE, a Phase 2 clinical trial evaluating RE104 for the treatment of adjustment disorder (AjD) in patients with cancer and other medical illnesses. Topline results from the study are anticipated in 2027.

With RE104, Reunion Neuroscience aims to offer patients an effective, safe and fast-acting psychotropic medication to relieve distress and dysfunction in patients with AjD. RE104 is the only psychedelic therapeutic in advanced clinical development for an AjD indication in the United States.

"AjD is an area of significant need for patients with cancer and other serious diseases, both because of the depressive and anxiety symptoms it introduces and the poorer medical outcomes it can engender," said Manish Agrawal, M.D., Co-Founder and Chief Executive Officer of Sunstone Therapies and REKINDLE investigator. "The unique mechanism of action of RE104, designed to deliver both rapid and sustained benefit, represents a promising new approach that may transform the treatment of patients suffering from AjD. I am proud to be part of this pioneering effort and look forward to evaluating RE104 in REKINDLE."

"Dosing the first patient in our REKINDLE Phase 2 trial marks a significant milestone in our mission to bring RE104 to patients living with underserved mental health disorders. AjD is a debilitating and underrecognized condition that affects the emotional well-being and medical outcomes of approximately 500,000 people in the United States each year, and for which there are currently no approved options," said Greg Mayes, President and Chief Executive Officer of Reunion Neuroscience. "Our confidence in RE104 is buoyed by positive topline data from the RECONNECT trial of RE104 for the treatment of PPD, which demonstrated RE104's ability to deliver rapid and safe symptom relief following a single dose. We look forward to bringing similar benefit to patients facing the emotional toll of cancer and other serious medical illnesses, as we expand our clinical development efforts and work to realize the full potential of RE104."

The REKINDLE Phase 2 clinical trial (NCT07002034) is a randomized, double-blind, parallel-group, dose-controlled clinical trial evaluating the safety and efficacy of RE104 for the treatment of AjD in adult patients with cancer and other medical illnesses. The primary endpoint of the trial is the change from baseline in total Montgomery-Åsberg Depression Rating Scale (MADRS) score, a clinician rated scale measuring depression severity. A key secondary endpoint of the trial is the change from baseline in the Hamilton Anxiety Scale (HAM-A), a clinician rated scale measuring anxiety severity. The study will also assess the safety and tolerability of RE104.

Reunion Neuroscience recently announced topline data from RECONNECT (NCT06342310), a multicenter, randomized, double-blind, dose-controlled Phase 2 clinical trial evaluating the safety and efficacy of a single subcutaneous dose of RE104 in adult female patients with moderate-to-severe PPD. RECONNECT met its primary endpoint, demonstrating a clinically-meaningful reduction in MADRS scores through Day 28, as well as a favorable safety and tolerability profile. These data support Reunion Neuroscience's plans to advance RE104 into a Phase 3 trial for the treatment of PPD in 2026. Reunion Neuroscience also plans to commence RECLAIM, a Phase 2 clinical trial in Generalized Anxiety Disorder (GAD), in the first quarter of 2026.

About Adjustment Disorder (AjD)
AjD is a mental health condition defined as a disproportionate reaction to a stressful life event or change, which impacts the ability to function and is characterized by depression, anxiety and/or other behavioral and mood disturbances. Serious medical illnesses are known to be a key precipitant of AjD; it is estimated that approximately 500,000 people in the United States are diagnosed with AjD each year following a medical or health-related stressor. Depressive and anxiety symptoms in medically ill patients with AjD can be associated with poorer medical outcomes, treatment compliance and quality of life as well as increased health care utilization. Current treatments for AjD are not consistently effective, and there are no therapies presently approved by the U.S. Food and Drug Administration (FDA) for its treatment.

Additional information on RE104's potential in AjD can be found in the white paper authored by Reunion Neuroscience, "Adjustment Disorder Associated With Medical Illness: Unmet Needs and Rationale for RE104 as a Novel Psychedelic Therapy."

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 shorter acute psychoactive experience when compared to longer experience duration psychedelics such as 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.

For further information:
IR Inquiries:
Hannah Deresiewicz
Precision AQ
hannah.deresiewicz@precisionaq.com

PR Inquiries:
Ashley Murphy
Precision AQ
ashley.murphy@precisonaq.com