Reunion Neuroscience Inc. Provides 2023 Corporate Update

Company Plans to Report Phase 1 Interim Analysis for RE104 in Q1 2023 and Include Data Differentiating its Safety, Tolerability and Pharmacodynamic Profile from Other Psychedelics in Clinical Development

On Track to Dose First Patient in Phase 2 Postpartum Depression Study in 2H 2023

President and CEO Presenting at Biotech Showcase in San Francisco on Jan. 9

TORONTO, Jan. 04, 2023 (GLOBE NEWSWIRE) -- Reunion Neuroscience Inc. (NASDAQ: REUN, TSX: REUN) ("Reunion" or "the Company"), a biopharmaceutical company committed to developing innovative and patented therapeutic solutions for underserved mental health conditions, today provided a corporate update for 2023 as it continues to advance its lead asset, RE104, through clinical development. As a proprietary, novel serotonergic psychedelic compound designed uniquely as a 4-OH-DiPT prodrug, RE104 is in development as a potential fast-acting, durable treatment for patients suffering from postpartum depression (PPD) and other mental health conditions.

Reunion plans to report a preplanned interim analysis on 32 subjects from its first-in-human Phase 1 trial for RE104 in Q1 2023. The study aims to address three important questions to differentiate RE104 from its therapeutic class: (1) What is the safety and tolerability profile of this unique 4-OH-DiPT prodrug? (2) What is the onset and duration of the psychoactive experience and pharmacokinetic profile of RE104 over a range of dose levels? and (3) At what dose level of RE104 do most subjects achieve a "complete mystical experience" while maintaining an acceptable safety and tolerability profile?

A complete mystical experience, as measured by the validated MEQ30, has been shown to correlate with a psychedelic treatment response in clinical trials of patients with depression, anxiety and substance use disorder [1-3]. The Company plans to share detailed results from its Phase 1 study at a major medical meeting in the first half of 2023.

The Company intends to include a review and discussion of the Phase 1 interim results in a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) intended for the first half of 2023. The output of the FDA meeting will support plans for initiating a randomized Phase 2 study evaluating RE104 versus placebo in the treatment of women with PPD in the second half of 2023. It is anticipated that the multicenter trial will enroll approximately 40 patients from 20 centers across North America. Once the PPD Phase 2 program is in progress, Reunion plans to share its continued RE104 development strategy in pursuit of treating additional indications.

PPD represents a priority clinical development opportunity with a high unmet need for new therapeutic options. One in eight mothers experience PPD, and there remains only one FDA-approved treatment for the condition, which requires an inpatient hospital stay to support administration. Selective serotonin reuptake inhibitors (SSRIs) are commonly prescribed for PPD, but they often take weeks to impart possible benefits, are not specifically approved for use in this setting and commonly require a trial of multiple SSRIs to find an effective solution.

As a novel serotonergic psychedelic, single-dose RE104 could potentially provide mothers with fast relief and a quick return to breastfeeding (24 to 48 hours) due to the asset's anticipated short psychoactive state (less than four hours), durable efficacy and rapid washout period.

Reunion President and CEO Greg Mayes will discuss these updates as part of his Biotech Showcase presentation in San Francisco, taking place on Monday, Jan. 9, at 2 p.m. PT.

"We believe RE104 is unlike any other psychedelic asset currently in clinical development to treat mental health conditions. As such, it has the potential to offer new hope to patients around the world – particularly women and mothers – who desperately need a better solution than the current standard of care," said Mr. Mayes. "Additionally, once the Company starts dosing patients in its Phase 2 study for PPD, it aims to select and pursue a second indication for RE104, as we believe that the asset holds immense promise as an innovative treatment for several other mental health conditions with high unmet medical needs. We look forward to a busy 2023 as we continue in our efforts to meet the increased demand for mental health treatments in a new, safe and highly effective manner."

1 Barrett FS, Johnson MQ, Griffiths RR. Validation of the revised Mystical Experience Questionnaire in experimental sessions with psilocybin. J Psychopharmacol. 2015;29(11):1182-1190. Read more

2 Yaden DB and Griffiths RR. The subjective effects of psychedelics are necessary for their enduring therapeutic effects. ACS Pharmacol Transl Sci. 2021;4(2):568-572. Read more

3 Garcia-Romeu A, Griffiths RR, Johnson MW. Psilocybin-occasioned mystical experiences in the treatment of tobacco addiction. Current Drug Abuse Reviews. 2014;7:157-164

About Reunion Neuroscience Inc.
Reunion is committed to developing innovative therapeutic solutions for underserved mental health conditions. The Company's lead asset, RE104, is a proprietary, novel serotonergic psychedelic compound being developed as a potential fast-acting and durable treatment for patients suffering from postpartum depression and other mental health conditions. The U.S. Patent and Trademark Office has granted the Company a patent for the claims related to RE104, granting it exclusive rights to the composition of matter, use and manufacturing of a family of hemi-ester compounds of hydroxytryptamines, including RE104. The patent will provide protection until 2041. Reunion is also developing the RE200 series, which includes compounds with potential for more selective serotonin receptor activity with reduced psychoactivity for potential use in more chronic treatment paradigms and indications.

Cautionary Note Regarding Forward-Looking Information

This release includes forward-looking information (within the meaning of Canadian securities laws and within the meaning of the United States Private Securities Litigation Reform Act of 1995) regarding Reunion and its business. Often but not always, forward-looking information can be identified by the use of words such as "expect", "intends", "anticipates", “plans”, "believes" or variations (including negative variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would", “should” or "will" be taken, occur or be achieved. Such statements are based on the current expectations and views of future events of the management of Reunion and are based on assumptions and subject to risks and uncertainties, many of which are beyond Reunion’s control. Although the management of Reunion believes that the assumptions underlying these statements are reasonable, they may prove to be incorrect. The forward-looking events and circumstances discussed in this release may not occur and could differ materially as a result of known and unknown risk factors and uncertainties affecting the companies, including the funds available to Reunion and the use of such funds, the timing, completion and potential outcome of testing and research on Reunion’s drug trial candidates, RE104 and the RE 200 Series, including the ability to recruit patients, to retain and identify clinical partners, and to optimize dosage amounts, the likelihood and ability of Reunion to complete an investigational new drug application and obtain regulatory approvals, as required, prior to initiating further clinical trials for RE104 and molecules within the RE200 Series, the ability of Reunion to meet eligibility requirements for clinical testing and through to more complex clinical trials, the ability of Reunion to protect and expand its intellectual property portfolio, the performance of Reunion’s affiliate, Field Trip Health & Wellness Ltd., the ability of Reunion to produce and supply its drug trial candidates, market conditions, economic factors, management's ability to manage and to operate the business, the equity markets generally and this and other Risk Factors disclosed in Reunion’s public filings available on the SEDAR website at www.sedar.com and on the EDGAR section of the SEC’s website at www.sec.gov. Although Reunion has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. Accordingly, readers should not place undue reliance on any forward-looking statements or information. No forward-looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made (or such earlier date, if identified) and Reunion does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise. Additional information relating to Reunion, including its Annual Information Form and Risk Factors, can be located on the SEDAR website at www.sedar.com and on the EDGAR section of the SEC’s website at www.sec.gov.

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities.

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