Reunion Neuroscience Inc. Completes Interim Data Analysis for Phase 1 Clinical Trial with Novel Serotonergic Psychedelic RE104

First-in-Human Findings Highlight RE104's Strong Safety and Differentiated Pharmacodynamic Profile, Setting Stage for Initiation of Phase 2 Development in Postpartum Depression

TORONTO, Jan. 09, 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 announced that the Company has completed the interim data analysis for its Phase 1 clinical trial with lead asset RE104, a unique 4-OH-DiPT prodrug. RE104 is a proprietary, novel serotonergic psychedelic compound that Reunion is developing as a potential fast-acting and durable treatment for patients suffering from postpartum depression and other mental health conditions.

In this first-in-human, Phase 1 study, RE104 was shown to be safe and well tolerated, with no serious or severe adverse events. The interim analysis included 32 healthy volunteers across four ascending dose cohorts, with two of the eight subjects in each cohort receiving placebo. RE104 showed robust and pervasive pharmacodynamic effects with a shorter duration of psychedelic experience relative to published data with psilocybin (approximately three to four hours for RE104 versus six to eight hours for psilocybin).[1-2]

Reunion also identified a dose level whereby the majority of participants receiving a single administration of RE104 achieved a "complete mystical experience," defined as a score of at least 60 percent in each of the four domains of the validated Mystical Experience Questionnaire (MEQ30). A complete mystical experience has been shown to correlate with psychedelic treatment responses in clinical trials of patients with depression, anxiety and substance use disorder.[3-5]

Reunion plans to share results from its Phase 1 study with the U.S. Food and Drug Administration (FDA) as part of a pre-Investigational New Drug (IND) meeting in preparation for Phase 2 development in postpartum depression. The Company will also submit the data to an upcoming 2023 major medical congress.

While completing the preplanned interim analysis, and per the recommendation of the Safety Review Committee (SRC), Reunion has continued with dose escalation and initiated a fifth cohort. The Phase 1 protocol also includes the option to dose a sixth cohort with eight subjects should the SRC or the Company seek additional safety, pharmacokinetics and pharmacodynamics data.

"We are extremely encouraged by the interim data from our Phase 1 clinical trial, as we've been able to identify a dose at which most participants had a short-duration, but complete, mystical experience without any serious or severe adverse events," said Greg Mayes, President and CEO, Reunion Neuroscience. "We are confident that this data provides robust justification for selecting a dose of RE104 that could yield clinical efficacy in the treatment of postpartum depression."

Mr. Mayes continued, "Innovation in the development of mental health treatment is severely lacking and has failed to provide meaningful change in how we approach these all-too-common conditions, especially with respect to women's mental health. We are eager to introduce a new psychedelic compound with significant potential advantages for these patients. The Company looks forward to unveiling the full Phase 1 dataset in the first half of 2023 and will continue to forge ahead in our mission to transform mental health treatment for the millions of people suffering worldwide."

Mr. Mayes will discuss these results as part of his Biotech Showcase presentation in San Francisco, taking place on Monday, Jan. 9, at 2 p.m. PT.

1 Carbonaro TM, Johnson MW, Hurwitz E, Griffiths RR. Double-blind comparison of the two hallucinogens psilocybin and dextromethorphan: similarities and differences in subjective experiences. Psychopharmacology (Berl). 2018;235(2):521-534. doi: 10.1007/s00213-017-4769-4. Epub 2017 Nov 7.

2 Goodwin GM, Aaronson ST, Alvarez O et al. Single-dose psilocybin for a treatment-resistant episode of major depression. N Engl J Med. 2022;187:1637-48.

3 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.

4 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.

5 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.

Neither the Toronto Stock Exchange, nor its Regulation Services Provider, have approved the contents of this release or accept responsibility for the adequacy or accuracy of this release.

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