December 19, 2023

NRx Pharmaceuticals Announces Signing of a Data and Technical Information Agreement with Columbia University Accessing Key Data Demonstrating Efficacy and Safety of Intravenous Ketamine for the Treatment of Suicidal Depression

- *Ketamine, an NMDA blocker, was highly effective compared to active comparator in rapidly reducing Suicidality (p=0.0003)*
- *This study represents the second well-controlled trial NRx has licensed supporting the use of IV Ketamine in suicidal depression*
- *NRx plans to present the data from these two trials to FDA in support of a New Drug Application to be filed in q1 2024*

RADNOR, Pa., Dec. 19, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced that it has signed a License Data and Technical Information Agreement with Columbia University for rights to data from a randomized, active-controlled trial of 80 patients hospitalized for Acute Suicidality in Depression. This represents NRx's second well-controlled trial demonstrating the efficacy of IV Ketamine in this indication.

In this trial, Dr. Michael Grunebaum and colleagues demonstrated a rapid and statistically significant reduction in Suicidal Ideation (SSI) at day 1 (p=0.0003) and in depression (P=0.0234), as measured by the Profile of Mood States (POMS) among patients randomized to IV Ketamine compared to those randomized to midazolam. This trial was published in the American Journal of Psychiatry https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5880701/.

These data mirror the results recently reported by a French consortium of hospitals who tested ketamine vs. placebo in acutely suicidal patients. NRx established a similar data licensing agreement in September, 2023 (NRx Ketamine Data Sharing, France). The study was published in the British Medical Journal (*BMJ* 2022; 376 doi: https://doi.org/10.1136/bmj-2021-067194).

The company and its regulatory counsel believe these two well-controlled trials meet the regulatory standard for a New Drug Application (NDA) filing in early 2024. This filing will include manufacturing and stability data from the Company's partnership with Nephron Pharmaceuticals (West Columbia, SC).

"We at NRx are delighted to partner with the thought leaders at Columbia University to help seek FDA approval for this extraordinary public health need. Until now, the only FDA-approved treatment for suicidal depression has been electroshock therapy (ECT). Recent literature suggests that ketamine may actually be superior to ECT in reducing suicidal ideation, while certainly having a more benign side effect profile," said Dr. Jonathan Javitt, Founder and Chief Scientist of NRx Pharmaceuticals. "Although ketamine is widely used off-label in the United States and is considered standard of care by some professionals, until it is labeled for treating depression and suicidality it will be widely accessible only to those patients able to pay out of pocket for their care and will continue to be subject to various warnings about off label use of a controlled substance."

Additional information about this initiative can be found on the Company's website *Ketamine FAQs.*

About NRx Pharmaceuticals

NRx Pharmaceuticals is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal bipolar depression, chronic pain and PTSD. The Company is developing NRX-101, an FDA-designated investigational Breakthrough Therapy for suicidal treatment-resistant bipolar depression and chronic pain. NRx has partnered with Alvogen Pharmaceuticals around the development and marketing of NRX-101 for the treatment of suicidal bipolar depression. NRX-101 additionally has potential to act as a non-opioid treatment for chronic pain.

NRx has recently announced plans to submit a New Drug Application for ketamine in the treatment of suicidal depression, based on results of well-controlled clinical trials conducted under the auspices of the US National Institutes of Health and newly obtained data from French health authorities, licensed under a data sharing agreement. NRx was awarded Fast Track Designation for development of ketamine (NRX-100) by the US FDA as part of a protocol to treat patients with acute suicidality.

Cautionary Note Regarding Forward-Looking Statements

This announcement of NRx Pharmaceuticals, Inc. includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995, which may include, but are not limited to, statements regarding our financial outlook, product development, business prospects, and market and industry trends and conditions, as well as the Company's strategies, plans, objectives, and goals. These forward-looking statements are based on current beliefs, expectations, estimates, forecasts, and projections of, as well as assumptions made by, and information currently available to, the Company's management.

The Company assumes no obligation to revise any forward-looking statement, whether as a result of new information, future events or otherwise. Accordingly, you should not place reliance on any forward-looking statement, and all forward-looking statements are herein qualified by reference to the cautionary statements set forth above.

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