NRX Pharmaceuticals Announces Data Sharing Agreement Demonstrating Efficacy and Safety of Intravenous Ketamine for the Treatment of Suicidal Bipolar Depression

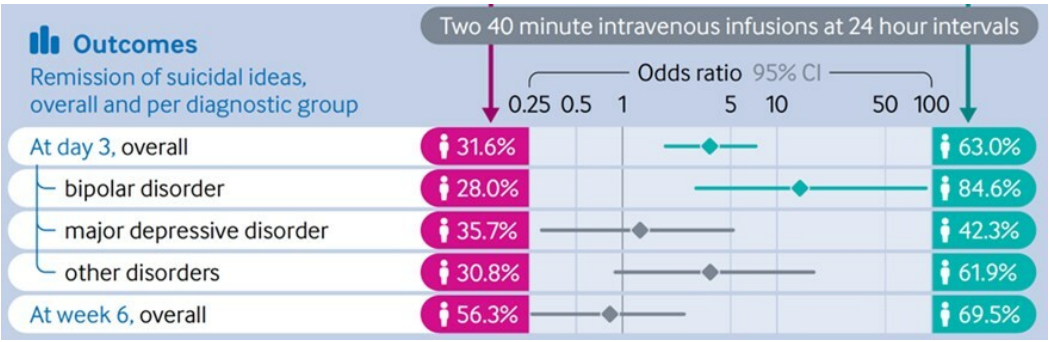
September 15, 2023

- *Ketamine, an NMDA blocker, was highly effective in Bipolar subgroup (p<0.001)*
- *NRx plans to present the data to FDA with a goal of identifying a path to an NDA*

RADNOR, Pa., Sept. 15, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced that it has signed a data sharing agreement with the study leadership of a randomized, placebo-controlled trial of 156 patients hospitalized for Acute Suicidality and Depression in 7 French Government Hospitals.

This trial, conducted under International Good Clinical Practices and Helsinki standards demonstrated a dramatic and statistically-significant reduction in suicidal ideation and depression (P<.0001) among patients randomized to intravenous racemic ketamine, compared to those randomized to placebo. The trial reached its primary endpoint for all patients and demonstrated the largest effect among the subgroup with bipolar depression (84% vs 28% remission, drug vs. placebo; p<0.0001; Odds ratio 14).

The top line data from this trial were published in the British Medical Journal



(*BMJ* 2022; 376 doi: https://doi.org/10.1136/bmj-2021-067194) and additional data reports are planned. The efficacy demonstrated confirms earlier, smaller trials conducted in the United States and elsewhere.

As disclosed previously, NRx met with the FDA in January 2023 at which time the FDA requested randomized, placebo-controlled data in support of intravenous ketamine for acute suicidality in the inpatient setting. Such trials are extraordinarily complex to organize and generally require Government support. In this case, NRx approached the Fondation FundaMental, led by Prof. Marion Leboyer, MD, PhD, who served on the NRx Scientific Advisory Board and facilitated establishing the current Data Sharing Agreement.

Under this agreement, NRx has translated the clinical study report, which will be submitted to FDA and is converting the electronic, patient level data files to a form suitable for FDA review. NRx plans to meet with FDA in the coming months to discuss a regulatory path for the use of ketamine to treat patients with Bipolar Depression and Acute Suicidal Ideation and Behavior.

"We at NRx are honored that the study leadership has agreed to share these landmark data so that they may be submitted to and reviewed by the US FDA," said Dr. Jonathan Javitt, Founder and Chief Scientist of NRx Pharmaceuticals. "We look forward to a fruitful ongoing collaboration with Prof. Abbar and his study team leadership for the benefit of patients everywhere."

About NRX-101

NRX-101, a fixed dose combination of D-cycloserine and lurasidone, has been granted Fast Track Designation, Breakthrough Therapy Designation, a Special Protocol Agreement, and a Biomarker Letter of Support from the FDA for S-TRBD. Additionally, the product is being developed in chronic pain and PTSD.

Up to 50% of individuals with bipolar disorder attempt suicide over their lifetime, and estimates indicate that up to 20% may succumb to suicide. The only FDA-approved treatment for patients with treatment-resistant suicidal bipolar depression remains electroconvulsive therapy.

Conventional antidepressants can increase the risk of suicide in certain patients; hence their labels contain a warning to that effect. NRX-101 is a patented, oral, fixed dose combination of D-cycloserine and lurasidone, neither of which has shown addiction potential in preclinical models. Based on the results of a Phase 2 proof-of-concept study, NRX-101 received Breakthrough Therapy Designation from the FDA for the treatment of severe bipolar depression in patients with ASIB after initial stabilization with ketamine or other effective therapy.

NRX-101 is one of the first oral antidepressants currently in late-stage clinical studies targeting the NMDA-receptor in the brain, which represents potentially a key new mechanism to treat depression with and without suicidality, as well as chronic pain, PTSD and other indications.

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's lead program NRX-101, an oral, fixed-dose combination of D-cycloserine and lurasidone, targets the brain's N-methyl-D-aspartate (NMDA) receptor and is being investigated in a Phase 2b/3 clinical trial for suicidal treatment-resistant bipolar depression (S-TRBD), which includes patients with both acute and sub-acute suicidality, an indication for which the only approved treatment is electroshock therapy. The Company has partnered with Alvogen Pharmaceuticals, who owns the worldwide rights to NRX-101 for treatment of S-TRBD, to help bring NRX-101 to a global population of patients with unmet medical need. NRx Pharmaceuticals is currently exploring NRX-101's potential to act as a non-opioid chronic pain treatment option and is continuing to plan to enroll patients in an Israeli-based trial of patients suffering from post-traumatic stress disorder with depression and 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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