NRx Pharmaceuticals Initiates Phase 3 Trial Treating Patients with Bipolar Depression with Acute Suicidality - First Clinical Site Contracted

January 3, 2023

- First investigational drug for patients with Severe Bipolar Depression and Acute Suicidal Ideation/Behavior, a high unmet medical need
- Company received Breakthrough Therapy Designation and a Special Protocol Assessment ("SPA") for this trial helping to mitigate risks and accelerate the timing of this NRX-101 development program
- First trial site has been contracted with others expected in near future, first dosing of patients is expected in early 2023
- Company to meet with research analysts and investors in conjunction with the upcoming JP Morgan Healthcare Conference

RADNOR, Pa., Jan. 3, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced that its first clinical trial site has been contracted (with others expected in near future) and that first dosing of patients is expected in early 2023. This Phase 3 clinical trial of NRX-101 is for the treatment of Severe Bipolar Depression with Acute Suicidal Ideation and Behavior ("SBD-ASIB"), a lethal condition that currently takes the lives of thousands of Americans each year. NRX-101 is the first investigational medicine to target this condition, for which the only currently approved treatment is Electroconvulsive Therapy.

Based on preliminary efficacy demonstrated in the Company's Phase 2 STABIL-B trial1, the FDA awarded Breakthrough Therapy Designation to NRX-101 in 2018. The Company subsequently received an FDA agreement for the Phase 3 trial under a Special Protocol Assessment which indicated that "based on the information submitted [FDA] agrees that the design and planned analysis of your study adequately address the objectives necessary to support a regulatory submission."

To strengthen compliance, the Company is using electronic compliance monitoring. Additionally, the Company will perform independent internal confirmation of depression and suicidality ratings as was done in the STABIL-B trial. In that prior trial, these methods enabled a high compliance with study medication and high concordance between the psychometric ratings ascertained at study sites and those confirmed by the Company's team of psychometric raters.

A Type B meeting with the FDA's Psychiatry Division is scheduled in mid-January 2023. The purpose of this meeting is to align on the registration strategy for NRX-101 in the initial indication for treatment of adults with SBP-ASIB.

Mr. Stephen Willard, JD, CEO of NRx stated, "As we continue to lose lives to suicide, there is no approved medicine to treat suicidal bipolar depression. Somewhere in America, a person attempts suicide every 27 seconds. We at NRx aim to replicate by year end a positive risk/benefit in our Phase 3 study as was achieved in the STABIL-B trial. We look forward to our meetings with research analysts and investors in conjunction with the upcoming JP Morgan Healthcare Conference."

About NRx Pharmaceuticals

Clinical-stage biopharmaceutical company developing therapeutics for the treatment of central nervous system disorders, specifically suicidal depression and post-traumatic stress disorder (PTSD). The company's lead program NRX-101, an oral, fixed-dose combination of D-cycloserine and lurasidone, targets the brain's NMDA receptor and is being investigated in a Phase 3 trial under an FDA Special Protocol Agreement and Breakthrough Therapy Designation in patients with bipolar depression and suicidal ideation, an indication for which the only approved treatment is electroshock therapy. NRx Pharmaceuticals has also initiated a Phase 2b clinical trial in patients with Sub-Acute Suicidality, a substantially broader indication. The Breakthrough Therapy Designation and Special Protocol Agreement were awarded by the FDA based on the Company's prior STABIL-B trial that demonstrated substantial improvement over available therapy in reducing depression and suicidality compared to placebo when patients were treated with NRX-101 after a single dose of ketamine.

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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1Nierenberg, et. al https://www.medrxiv.org/content/10.1101/2022.08.11.22278658v1.full

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