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# NRx Pharmaceuticals Provides Progress Update on Interactions with the FDA regarding Path to NDA Submission for NRX-101

RADNOR, Pa., Jan. 19, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage central nervous system (CNS) biopharmaceutical company, today announced that it had a meeting and a written response from the Food and Drug Administration (FDA) last week regarding its lead compound, NRX-101.

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In response to a request for Type C guidance on the chemistry, manufacturing and controls (CMC) aspects of the NRX-101 program, FDA provided Written Responses on January 10th. As previously announced in October 2022, an updated NRX-101 module 3 was submitted to add the intended commercial manufacturer to the IND. With FDA's written response, it appears that NRx Pharmaceuticals has reached alignment with the FDA regarding its proposed registration manufacturing plan.

A Type B meeting with the FDA was held on January 11, 2023.

Minutes of the meeting are expected to be available in approximately 30 days.

"We appreciate the FDA's ongoing guidance and support under the Breakthrough Therapy Designation associated with NRX-101 as well the previously issued Special Protocol Agreement for the treatment of Bipolar Depression in Patients with Acute Suicidal Ideation and Behavior. Our quest is to develop the first medicine to treat patients with suicidal depression and aim to develop a new drug therapy for post-traumatic stress disorder (PTSD)", said Stephen Willard, chief executive officer of NRx Pharmaceuticals. "We look forward to continued discussions addressing our mutual goal to treat bipolar depression and suicidality at a time when someone in the United States attempts suicide every 27 seconds."

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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