NRx Pharmaceuticals Produces First Phase 3-stage NRX-101 Drug Made Using Commercial Process

November 9, 2022

- Manufacturing files submitted to U.S. Food and Drug Administration
- The company has now completed its transition to U.S.-based manufacturing
- NRX-101 is now manufactured via a commercial-stage process

RADNOR, Pa., Nov. 9, 2022 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), ("NRx Pharmaceuticals" or the "Company"), a clinical-stage CNS biopharmaceutical company, today announced the release of the first batches manufactured in the U.S. of NRX-101, its Phase 3-ready investigational drug, targeting suicidal bipolar depression and with future study plans for post-traumatic stress disorder (PTSD). The Company plans to initiate a phase 3 trial targeting bipolar depression in patients with acute suicidal ideation and behavior (ASIB) in the near term. Due to pandemic-related supply chain disruptions, the Company invested in developing commercial manufacturing processes in the U.S. prior to initiating this registrational study. NRx Pharmaceuticals has opted to use this commercial process material in its anticipated registrational clinical study. Having this new manufacturing capability could shorten the time to market availability for NRX-101. A full technology transfer was recently completed, and the corresponding manufacturing file update was submitted to the FDA.

NRX-101 is a patented, oral, fixed dose combination of D-cycloserine and lurasidone. It is the first oral drug to target suicidal bipolar depression, a significant unmet medical need, as it is estimated that approximately 50% of the 7 million individuals with bipolar disorder in the U.S. attempt suicide over their lifetime, mostly during the depressive phases. The only FDA-approved treatment for this condition is electroshock therapy. Currently approved drugs for bipolar depression carry a warning of a potential increase in the risk of suicide in certain populations.

The Company completed an initial phase 2 trial of NRX-101 in 2018 and demonstrated a statistically significant reduction in both measures of depression (P<.03) and suicidality (P<.03) compared to lurasidone alone; patients in this study were initially stabilized with a single infusion of ketamine. Lurasidone is the U.S. market sales leader in the treatment of bipolar depression. These developments led to NRX-101 being granted Breakthrough Therapy Designation and a Special Protocol Agreement from the FDA for the treatment of Severe Bipolar Depression in patients with Acute Suicidal Ideation and Behavior.

"Someone attempts suicide every 27 seconds in the United States and NRx Pharmaceuticals is committed to bringing patients the first safe, oral drug that might help to save lives in this lethal condition. NRx Pharmaceuticals made the initial investment for the building of a U.S. commercial manufacturing capability in order to offer the drug to patients at the earliest possible moment, should NRx Pharmaceuticals demonstrate efficacy and safety in the upcoming phase 3 clinical trial," said Stephen Willard, JD, Chief Executive Officer of NRx Pharmaceuticals.

About NRx Pharmaceuticals, Inc.

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, a 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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