February 2, 2023

NRx Pharmaceuticals Reports Recommendations of Data Safety Monitoring Board for Trial of NRX-101 in Patients with Severe Bipolar Depression and Subacute Suicidal Ideation or Behavior

- The Independent Data Safety Monitoring Board identified no safety concerns and issued a recommendation to continue trial enrollment.
- No treatment-related Serious Adverse Events with first 50 enrolled clinical trial participants

RADNOR, Pa., Feb. 2, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today reported the recommendations of an independent Data Safety Monitoring Board (DSMB) which reviewed the safety findings of the first fifty enrolled participants in the Company's phase 2 clinical trial of NRX-101 for the treatment of Severe Bipolar Depression and Subacute Suicidal Ideation or Behavior (www.clinicaltrials.gov NCT NCT03395392). NRX-101 is a proprietary fixed dose combination of D-cycloserine and lurasidone. It is the only antidepressant currently in clinicals trials for patients with Bipolar Depression with acute or sub-acute suicidality, which also entails an NMDA component, similar to AUVELITY® and SPRAVATO®.

The Independent Data Safety Monitoring Board identified no safety concerns and issued a recommendation to continue trial

Unlike the Company's previously completed Phase 2 study which enrolled acutely suicidal patients, this current Phase 2 study addresses the needs of the much larger population of patients with bipolar depression and sub-acute levels of suicidality, i.e., not requiring stabilization in a clinical setting, who are cared for in the outpatient setting, including doctors' offices, community mental health centers, and outpatient clinics. The Company's Bipolar Depression with Acute Suicidal Ideation or Behavior (ASIB) study requires that patients first be stabilized in a clinical setting, patients enrolled in this current Phase 2 trial are randomly assigned to NRX-101 or lurasidone – a widely used drug indicated for the treatment of bipolar depression.

The DSMB recommended that enrollment in the trial continue as planned and identified no drug-related Serious Adverse Events or other safety issues of concern. The Company anticipates that the DSMB will examine unblinded study data in March 2023 to assess the study for safety, potential futility, and conditional power. The Company views today's safety finding as important because this is the first time, to the Company's knowledge that patients with bipolar depression and subacute suicidal ideation and behavior (i.e., present with an ideation score at a screening of 3 or 4 on the Columbia Suicide Severity Rating Scale (CSSR-S)) have been actively recruited into an outpatient clinical trial of a novel NMDA based antidepressant.

Mr. Stephen Willard, JD, Chief Executive Officer of NRx Pharmaceuticals stated, "In today's environment, there is no approved medicine to treat suicidal bipolar depression. Somewhere in America, someone attempts suicide every 27 seconds. We appreciate the DSMB's work in guiding us to continue this trial. We are now exploring a registrational path forward to serve this much larger group of individuals with bipolar depression and subacute levels of suicidality. This population of patients

encompasses a much larger proportion of the approximately 7 million individuals in America who have bipolar disease, half of whom are reported to attempt suicide at some point in their lives."

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.

CORPORATE CONTACT
Molly Cogan
Sr. Director, Global Communications
mcogan@nrxpharma.com

INVESTOR RELATIONS
Suzanne Messere
Investor Relations

*suzanne.messere@sternir.com*mailto:

SOURCE NRx Pharmaceuticals, Inc.

View original content to download multimedia https://ir.nrxpharma.com/2023-02-02-NRx-Pharmaceuticals-Reports-Recommendations-of-Data-Safety-Monitoring-Board-for-Trial-of-NRX-101-in-Patients-with-Severe-Bipolar-Depression-and-Subacute-Suicidal-Ideation-or-Behavior