January 22, 2024

NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) Announces Completion of Enrollment of its Phase 2b/3 Trial of NRX-101 in Suicidal Treatment Resistant Bipolar Depression

- *Exceeded originally target enrollment (70) with n=74*
- *Last patient, last visit expected in approximately six weeks; data to follow shortly thereafter*
- *Positive data triggers milestone payment from Alvogen, as previously announced.*

RADNOR, Pa., Jan. 22, 2024 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced completion of enrollment in its Phase 2b/3 study of NRX-101, the Company's patented combination of the NMDA antagonist D-cycloserine and lurasidone, in Suicidal Treatment Resistant Bipolar Depression. Enrollment of 74 patients exceeded the original target of 70 patients, in order to enhance statistical power of the study. As previously disclosed, positive data from this trial triggers a milestone payment from Alvogen. Alvogen will then be responsible for further development and commercialization costs for this program.

"To our knowledge, NRX-101 is the first and only oral medication to have demonstrated reduced suicidal ideation in patients with bipolar depression, a lethal disease that claims the lives of one in five who live with it. On the basis of our previous trial, it was awarded Breakthrough Therapy Designation by the FDA and we aim to confirm its effect on depression and suicidal ideation in this trial. We thank our study investigators, dedicated trial sites, and of course, incredible patients," said Dr. Jonathan Javitt, Founder, Chairman and Chief Scientist of NRx Pharmaceuticals. "We hope to bring a lifesaving home-use oral medicine to patients whose only currently-approved treatment is electroconvulsive therapy (ECT)."

The Phase 2b/3 trial (www.clinicaltrials.gov NCT 03395392) enrolled 74 patients with suicidal bipolar depression. This is a randomized, prospective, multicenter, double-blind study comparing NRX-101 to lurasidone over six weeks. The Principal Investigator is Prof. Andrew Nierenberg of Harvard Massachusetts General Hospital. The primary efficacy endpoint is reduction in depression as measured on the MADRS scale and the secondary endpoint is reduction of suicidal ideation as measured by the Clinical Global Impression Suicidality Scale (CGI-SS). As previously disclosed, treatment compliance and concordance of local raters to central raters scores was in excess of 94%, well above the industry standard that is normally seen in CNS trials.

Top-line results are expected later this quarter.

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 is developing NRX-101, an FDA-designated investigational Breakthrough Therapy for suicidal treatment-resistant bipolar depression and chronic pain. NRx has partnered with Alvogen Pharmaceuticals around the development and marketing of NRX-101 for the treatment of suicidal bipolar depression. NRX-101 additionally has potential to act as a non-opioid treatment for chronic pain, as well as a treatment for complicated UTI.

NRx has recently announced plans to submit a New Drug Application for ketamine in the treatment of suicidal depression, based on results of well-controlled clinical trials conducted under the auspices of the US National

Institutes of Health and newly obtained data from French health authorities, licensed under a data sharing agreement. NRx was awarded Fast Track Designation for development of ketamine (NRX-100) by the US FDA as part of a protocol to treat patients with acute 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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