NRx Pharmaceuticals (NASDAQ: NRXP) Announces Last Patient, Last Visit in its Phase 2b/3 Trial of NRX-101 in Suicidal Treatment Resistant Bipolar Depression

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- Marks a major step in the development of what could be the first drug approved for Suicidal Bipolar Depression
- The study database is being cleaned and locked; statistical analysis and top-line data to follow shortly thereafter
- Study maintained 95% concordance rate between study sites and central raters on primary endpoint. No unexpected Serious Adverse Events were reported.
- Positive data and FDA comment would trigger the next $4 million milestone payment from partners Alvogen and Lotus and their assumption of development costs; agreement provides for up to $329 million in milestone payments and a royalty on Net Sales in the mid-teens

RADNOR, Pa., March 4, 2024 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced that the 74th and last evaluable patient has completed their day 42 visit 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. The database is being cleaned, finalized, and locked; statistical analysis will then be performed, with top-line data to follow shortly thereafter. 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.

NRX-101 has been awarded Breakthrough Therapy Designation, Fast Track Designation, a Biomarker Letter of Support, and a Special Protocol Agreement by the FDA for treatment of suicidal bipolar depression. It is the 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.

"This is the first clinical trial, to the company's knowledge, conducted among patients with suicidal bipolar depression in the outpatient setting. Our previous trial measured the ability of NRX-101 to maintain the anti-depressant and anti-suicidal effect of ketamine administered in the hospital setting. These patients, whose clinical need is urgent and extraordinary have routinely been excluded from the clinical trials of all previously-known anti-depressant drugs. said Dr. Jonathan Javitt, Founder, Chairman and Chief Scientist of NRx Pharmaceuticals. Although there were patients whose depression worsened and required hospitalization (we don't yet know whether they were on NRX-101 or comparator), patient safety was maintained, and no trial participant suffered a serious unexpected adverse outcome. Our thanks go out to our investigators, clinics, partners and, most importantly, our amazing patients and their families for seeing this study through to this important milestone," "

The Phase 2b/3 trial (www.clinicaltrials.gov NCT 03395392) 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 around the end of 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 and Lotus 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 HTX-100 (IV ketamine), through Hope Therapeutics, 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.

About HOPE Therapeutics, Inc.

HOPE Therapeutics, Inc. (www.hopetherapeutics.com) is a Specialty Pharmaceutical Company, wholly-owned by NRX Pharmaceuticals focused on development and marketing of an FDA-approved form of intravenous ketamine for the treatment of acute suicidality and depression together with a digital therapeutic-enabled platform designed to augment and preserve the clinical benefit of NMDA-targeted drug therapy.

Notice Regarding Forward-Looking Statements

The information contained herein includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These statements include, among others, statements regarding the proposed public offering and the timing and the use of the proceeds from the offering. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "look forward," and other similar expressions among others. These statements relate to future events or to the Company's future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond the Company's control and which could, and likely will, materially affect actual results, levels of activity, performance or achievements. Any forward-looking statement reflects the Company's current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy and liquidity. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's most recent Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. Investors and security holders are urged to read these documents free of charge on the SEC's website at http://www.sec.gov. Except as may be required by applicable law, The Company assumes no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, whether as a result of new information, future events or otherwise.

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