NRx Pharmaceuticals (Nasdaq:NRXP) Announces FDA Clearance to Proceed with Clinical Trial of NRX-101 in Combination with Robotic-enabled Transcranial Magnetic Stimulation in Patients with Depression and Suicidality

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- Preliminary research suggests that D-cycloserine significantly enhances the effect of Transcranial Magnetic Stimulation (TMS) Trial is planned to be conducted at a leading US academic teaching hospital, three HOPE Therapeutics Clinics, and two military treatment facilities
- Company targeting non-dilutive funding to support enrollment of 400 patients
- Should the trial yield successful results, D-cycloserine-augmented TMS could play a significant role in the readiness of first responders, military personnel, and others affected by Treatment-resistant Depression

WILMINGTON, Del., May 07, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals (Nasdaq:NRXP) announces receipt of clearance from the US Food and Drug Administration to initiate a clinical trial of NRX-101 (D-cycloserine/lurasidone fixed dose combination) vs. placebo in patients with depression and suicidality who are being treated with either Robotic-assisted Transcranial Magnetic Stimulation (TMS) or sham TMS. The placebo-controlled phase 2/3 trial is identified as “A Randomized, Double-Blind, Three-Arm Study of NRX-101 as Adjunctive Therapy to Active or Sham Transcranial Magnetic Stimulation in Adults with Treatment Resistant Major Depressive Disorder (MIND1).

The trial will be conducted by NRx Defense Systems, a subsidiary of NRx Pharmaceuticals. The randomized portion of the clinical trial will enroll 240 participants at a leading US academic teaching hospital and three planned study sites maintained by HOPE Therapeutics, Inc. An additional group of participants is planned to be enrolled at two United States Military Treatment Facilities. Study sites will be announced following approval by Institutional Review Boards.

The Principal Investigator of the MIND1 trial, Prof. Josh Brown, PhD, MD served as the Principal Investigator of predecessor Phase 1 and Phase 2 studies funded by the US Defense Advanced Research Projects Agency. The Company anticipates that the newly-approved trial will be supported through non-dilutive sources, given the implications of a short-term effective and noninvasive treatment for depression on force readiness within the military and first responder organizations. In addition to serving as the Company’s Chief Medical Innovation Officer Dr. Brown serves as an Assistant Professor of Psychiatry and Head of TMS Research at Harvard McClean Hospital.

The trial will be led organizationally by the President of NRx Defense Systems, Inc., Dr. Dennis K. McBride (CAPT, Medical Service Corps, Ret., US Navy), Distinguished Research Fellow, National Defense University, and former senior executive in the Office of the Secretary of Defense. Dr. McBride twice served as a Program Manager at the Defense Advanced Research Projects Agency. He has led, to highly successful transition, numerous medically complex projects from a wide range of research and development labs and offices in the US Department of War.

“We at NRx deeply appreciate the FDA’s support for this vital research initiative that has potential to address the well-known challenge of depression and suicide within our military and first-responder organizations. A short-term treatment that has the potential to restore vital personnel to duty without disqualifying antidepressant drugs would be a major advance with implications for the entire nation,” said Dr. McBride.

About NRx Pharmaceuticals, Inc.
NRx Pharmaceuticals, Inc. (www.nrxpharma.com), is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal depression, chronic pain, and PTSD. The Company is developing NRX-100 (preservative-free intravenous ketamine) and NRX-101, (oral D-cycloserine/lurasidone). NRX-100 has been awarded Fast Track Designation for the treatment of Suicidal ideation in Depression, including Bipolar Depression. NRX-101 has been awarded Breakthrough Therapy Designation for the treatment of suicidal bipolar depression. NRx has filed an Abbreviated New Drug Application (ANDA), and initiated a New Drug Application filing for NRX-100 for the treatment of suicidal ideation in patients with depression, including bipolar depression.

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. 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. The Company has reported regulatory milestones as they have been achieved but has not predicted the outcome of any future regulatory determination. 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, including uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy, and, among other things, 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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