NRx Pharmaceuticals (Nasdaq:NRXP) Announces Path to New Drug Application with Real World Data and Broader Proposed Indication for NRX-100 (ketamine) Following Type C FDA Meeting

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- NRx together with Osmind, Inc. conducted an in-person meeting attended by leadership of the FDA Division of Psychiatry Products and leadership of the FDA Center for Drug Evaluation and Research (CDER)
- Oral guidance received at the meeting provides a path to filing an application for New Drug Approval of NRX-100 under already-awarded Fast Track Designation based on existing clinical trial data and Real World Evidence
- Based on the guidance, NRx will seek a broader proposed indication for NRX-100 to serve patients with treatment-resistant depression who may have suicidality rather than only the subset with suicidality

WILMINGTON, Del., Feb. 17, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharmaceutical company, today announced that it has completed an in-person Type C guidance meeting at the headquarters of the US Food and Drug Administration. The meeting was attended by leaders of the FDA Division of Psychiatry Products, the FDA Office of Neuroscience, and the FDA Center for Drug Evaluation and Research.

Based on oral guidance received at the meeting, NRx believes it has a path to filing an application for New Drug Approval of NRX-100 (preservative-free ketamine) based on Substantial Evidence of Effectiveness derived from existing data from adequate and well controlled trials together with confirmatory evidence from more than 65,000 patients identified in the Real World Evidence dataset. NRx will additionally seek a broader indication to serve patients with treatment resistant depression in the context of suicidality, rather than only the subset of patients with suicidality.

The Companies will work collaboratively with the FDA in the coming weeks to finalize the statistical analysis protocol for the full 65,000 person Real World Evidence dataset under FDA's newly published guidance.

In preliminary comments ahead of meeting, FDA advised NRx that no additional nonclinical data would be required for review of NRx's New Drug Application and that no bridging studies would be needed to support NRx's preservative-free formulation compared to the currently-approved preservative-containing formulation of ketamine.

"We deeply appreciate the FDA's meeting with us at the leadership level and guiding us to pursue a New Drug Application for NRX-100 for the benefit of the millions of Americans who tragically form a plan to end their lives each year," said Dr. Jonathan Javitt, founder, Chairman, and CEO of NRx pharmaceuticals. Based on the guidance received, we will be using the clinical trial data already in hand together with the proposed Real World Data from Osmind, Inc., to apply for approval of a lifesaving drug to meet the needs of Americans, including Veterans and First Responders."

Additional details will be provided upon receipt of the final meeting minutes.

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 with an application for the Commissioner's National Priority Voucher Program 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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