NRx Pharmaceuticals (Nasdaq:NRXP) Confirms 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 has received confirmatory FDA minutes from in-person Type C meeting attended by leadership of FDA Division of Psychiatry, FDA Office of Neuroscience, and FDA Center for Drug Evaluation and Research.
- Minutes are consistent with previously announced oral guidance outlining a path to New Drug Approval of NRX-100 for a broadened indication of treating depression, including patients with suicidality.
- FDA confirmed willingness to review existing Adequate and Well Controlled Clinical Trial data as Substantial Evidence of Efficacy together with Real World Evidence from Osmind, Inc. as confirmatory evidence of efficacy.
- No additional clinical trials were requested.
- Company intends to sumbit its New Drug Application for NRX-100 by June 2026.

WILMINGTON, Del., March 16, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharmaceutical company, today announced that it has received confirmatory minutes from 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.

The minutes support FDA's willingness to review NRx's application for New Drug Approval of NRX-100 (preservative-free ketamine) based on Substantial Evidence of Effectiveness derived from existing adequate and well controlled trials. No additional clinical trials were requested. NRx agreed with FDA to submit existing patient-level data for review.

In the trials discussed with FDA, ketamine has demonstrated dramatic superiority to placebo and to active placebo, together with non-inferiority versus electroshock therapy. Moreover, ketamine has demonstrated statistically significant reduction in suicidal ideation. Notably, electroshock therapy, the only currently-approved treatment for suicidal ideation demonstrated a 30% incidence of memory loss, whereas ketamine did not.

The FDA minutes additionally confirm FDA's willingness to review Real World Evidence as confirmatory evidence of efficacy. Preliminary analysis of that Real World Evidence confirms the effectiveness of intravenous ketamine both in reducing depression and suicidal ideation.

Based on the meeting minutes, NRx will seek a primary indication to treat depression in patients with severe depression who may have suicidal ideation, in place of the Company's original plan to treat only those with suicidal ideation. According to the CDC, more than 16 million Americans experience depression each year and 3.6 million Americans contemplate suicide

FDA confirmed in the minutes 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, for which the Company anticipates at least three years of room temperature shelf stability.

"We deeply appreciate the FDA's supportive 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 with severe depression, millions of whom tragically form a plan to end their lives each year," said Dr. Jonathan Javitt, founder, Chairman, and CEO of NRx pharmaceuticals. "We look forward to a day when suicide is no longer the second leading cause of death in Americans under the age of 35 and to approval of a lifesaving drug to meet the needs of Americans, including Veterans and First Responders."

In addition to the pending New Drug Application for NRX-100 based on treatment of depression, NRx has a pending Abbreviated New Drug Application for the sale of preservative-free ketamine under its current label for use in anesthesia. As previously announced, FDA agreed to receive that application in September 2025 and assigned a Summer 2026 decision date.

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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