NRx Pharmaceuticals (Nasdaq:NRXP) Announces 70,000 Patient Data on Real World Use of Ketamine for Treatment of Suicidal Depression to be Submitted to the FDA in Support of NRX-100 Approval

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- NRX-100 (preservative-free ketamine) has been granted Fast Track Designation by FDA for treatment of suicidal ideation in patients with Depression and Bipolar Depression.
- Real-world evidence, consistent with FDA guidance, is supplied and generated by Osmind using its nationwide electronic medical records-derived dataset.
- Previously presented preliminary analysis of a 20,000 patient subset documented rapid resolution of depression and suicidality with initiation of intravenous ketamine.
- Analyses suggested that clinical response to intravenous ketamine is consistent with prior randomized trial data and compares favorably to currently-approved products.
- Results from an upcoming analysis of the full 70,000 patient Real World Data set will be presented to the FDA in support of Accelerated Approval.

WILMINGTON, Del., Jan. 14, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharmaceutical company, today announced that it has licensed Real World Evidence (RWE) drawn from over 70,000 patients in the United States who were treated with either intravenous ketamine or nasal S-ketamine for depression and suicidal ideation. The information is being submitted in support of NRx's application for Accelerated Approval of NRX-100 (preservative-free ketamine) under Fast Track Designation for Treatment of Suicidal Ideation in Depression and Bipolar Depression. Currently, there is no medicine approved to treat suicidal ideation and the only FDA-approved treatment today is Electroshock Therapy.

The RWE is provided by Osmind, a leading neuropsychiatry technology and medical records platform used by clinics across the United States. Through this collaboration, Osmind is supplying regulatory-grade real-world evidence (RWE) to the US Food and Drug Administration (FDA) to support NRx's application for Accelerated Approval of NRX-100 (preservative-free ketamine) as a treatment for suicidal ideation in depression, including bipolar depression.

Osmind offers an industry-leading real-world dataset on ketamine and esketamine with a large, diverse patient base and a comprehensive set of fit-for-purpose data variables spanning effectiveness and safety with longitudinal capture. This dataset includes nearly one million treatment sessions with ketamine or esketamine, hundreds of millions of datapoints of continuous vitals monitored during treatment, and differentiated data elements such as assessment of bladder symptoms and sedation.

A preliminary analysis of a subset of patients was presented by Osmind at the 2024 meeting of the American Society of Clinical Psychopharmacology.[1] Quantitative comparison to currently-approved products suggested a favorable clinical response. NRx is optimistic that when the full real-world dataset of over 70,000 patients is analyzed, the results will be clinically meaningful. In September 2025, FDA altered its policy to allow the submission of RWE that does not include personally-identifiable patient information, a policy shift that enables the submission of de-identified data from Osmind.

"We appreciate Osmind's partnership in sharing this 70,000 patient Real World dataset in support of NRX-100 approval by the FDA," said Jonathan Javitt, MD, MPH, Chairman and CEO of NRx Pharmaceuticals. "An American commits suicide every 11 minutes and ketamine has become widely used off label as a drug that has been seen to reduce suicidal ideation in clinical trials. Ketamine has been adopted within the military and veterans communities for this purpose. As a result, only Americans whose care is paid for by the military and the Veterans Administration, along with those who can pay out of pocket, are able to access this potentially valuable medicine. Those who rely on other health insurance are generally not eligible for reimbursement. We are in the process of applying to the FDA for Accelerated Approval of NRX-100 (preservative-free ketamine) to enable broader access of this potentially life-saving medicine under appropriate medical supervision."

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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[1] https://www.osmind.org/blog/esketamine-and-iv-ketamine-for-major-depression