NRx Pharmaceuticals Announces US Food and Drug Administration (FDA) Receipt of ANDA for KETAFREE™, a Preservative-Free IV Ketamine

December 2, 2025

- FDA has determined that NRx's Abbreviated New Drug Application (ANDA) is "substantially complete" and received for review. Assigned GDUFA goal date is July 29, 2026.
- NRx has applied to FDA for use of KETAFREE™ as a proprietary product name, which is subject to review. KETAFREE™ is the first preservative-free ketamine formulation that does not include potentially toxic preservatives used in current multidose presentations of ketamine.
- Current worldwide generic ketamine market is estimated at $750 million per year.
- NRx has manufactured initial registration lots of KETAFREE™ and is prepared to scale manufacturing to 1 million vials per month.
- NRx is awaiting a response to its Citizen Petition filed in August with the FDA seeking the removal of Benzethonium Chloride preservative from all forms of ketamine sold in the United States

WILMINGTON, Del., Dec. 02, 2025 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has received the Company's Abbreviated New Drug Application (ANDA) for KETAFREE™, a preservative-free intravenous ketamine formulation. The acknowledgement letter states that the FDA has "made a threshold determination that this ANDA is substantially complete" and issued a goal date of July 29, 2026 for completion of the final review with potential marketing approval.

"We appreciate FDA's careful review and are pleased that it has received our application for KETAFREE™, an important milestone in our effort to bring a single-patient, preservative-free presentation of ketamine to the patients and clinicians who depend on this medicine," said Jonathan Javitt, MD, MPH, Chairman and CEO of NRx Pharmaceuticals. "Current ketamine products are typically supplied in multi-dose vials that contain a preservative called Benzethonium Chloride (BZT) that is not recognized as safe by FDA and banned from hand cleansers and topical antiseptics.

BZT was originally added to ketamine and other sterile injectable products in the 1970s at a time when multidose vials of medication were used to treat several patients, a practice that is no longer allowed in US healthcare facilities. BZT is no longer added to new sterile products.

The current MAHA initiatives have called for review and removal of toxic substances from foods, drugs, and vaccines and KETAFREE™, is designed to align with those priorities. " KETAFREE™ is is intended for all currently approved ketamine indications and is manufactured in the United States, supporting national efforts to strengthen the domestic supply of critical medicines. In awarding a Commissioner's National Priority Voucher last month to a US-based manufacturer of ketamine active pharmaceutical ingredient (API) the FDA recognized the critical strategic nature of ketamine to the nation's drug supply.

KETAFREE™ is separate from NRx's New Drug Application for NRX-100, which is being developed as an innovative drug for the treatment of suicidal depression and has received Fast Track designation from the FDA. With the KETAFREE™ ANDA now received and deemed substantially complete, the next key milestone is completion of FDA review under the Generic Drug User Fee Amendments framework, with a GDUFA goal date of July 29, 2026. An approval on that timetable would potentially create meaningful 2026 approved drug sales with profitability in line with public markets analysts.

The Company continues to advance other elements of its pipeline and its development of HOPE Therapeutics clinics, a report on which will be presented at tomorrow's Noble Securities NOBLECON conference and available on the Company's website.

About NRx Pharmaceuticals, Inc.

NRx Pharmaceuticals, Inc. (www.nrxpharma.com), is a clinical-stage biopharmaceutical company focused on Neuroplastic Therapies for the treatment of central nervous system disorders, specifically suicidal depression, PTSD, anxiety, and Autism. The Company combines drug development with a best-in-class network of clinics (HOPE Therapeutics) offering medication management, Transcranial Magnetic Stimulation, and Hyperbaric Oxygen Therapy that combine to achieve rapid response and remission. NRx 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 for its preservative-free ketamine formulation and is anticipating a July 2026 launch.

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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