NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Announces Expanded Access Policy for NRX-100 (preservative-free ketamine)

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- *US Food and Drug Administration (FDA) has granted Fast Track designation for NRX-100 in the treatment of suicidal ideation in patients with depression, including bipolar depression.*
- *NRx Pharmaceuticals is making NRX-100 available on an expanded access basis upon physician request for patients with serious or life-threatening suicidal depression despite treatment with currently available therapy.*
- *Approximately 13 million adults seriously consider suicide each year, according to the CDC. An American dies from suicide every 11 minutes.*
- *Physicians may apply for expanded access on behalf of patients who meet expanded access criteria by writing to expandedaccess@nrxpharma.com. Further information may be viewed at https://www.nrxpharma.com/expandedaccess/nrx-100.*

WILMINGTON, Del., Aug. 27, 2025 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq:NRXP), a clinical-stage biopharmaceutical company, today announced its expanded access policy for NRX-100 (preservative-free ketamine) based on grant of Fast Track designation for NRX-100 in the treatment of suicidal ideation in patients with depression, including bipolar depression.

In granting the Fast Track designation, FDA made the determination that NRX-100 has the potential to address an unmet need, based on an assessment of the preliminary data contained in the Fast Track designation request. Accordingly, NRX-100 is available for expanded access to eligible patients. More about this program can be learned from the Reagan Udall Foundation, https://navigator.reaganudall.org/, which works in conjunction with the FDA to provide public information on expanded access medications.

Upon physician request, NRx Pharmaceuticals may make NRX-100 available to patients when certain conditions, including the following are met:

- The patient has a serious or life-threatening illness or condition and is either no longer responsive to or not able to tolerate any approved treatment option;
- The investigational drug is in active clinical development with sufficient data available to determine an appropriate dose and schedule for the patient's specific condition;
- A benefit-risk analysis, based on both the available clinical data as well as the requesting physician's assessment of the individual patient's condition and history, supports making the investigational drug available;
- Making the investigational drug available will not negatively impact or delay the conduct of clinical trials or regulatory review or approval of the investigational drug for broader patient access; and
- Adequate supply of the investigational drug is available.

"We at NRx recognize the urgent need to make NRX-100 available to patients with suicidal depression for whom approved therapies are not tolerated or effective. We look forward to participating in FDA's expanded access program and to serving patients in need as we endeavor to Bring Hope to Life," said Jonathan C. Javitt, MD, Chairman and CEO of NRx Pharmaceuticals.

Physicians wishing to obtain NRX-100 for their patients under the FDA Expanded Access Program should write to expandedaccess@nrxpharma.com or visit the Company's web page at https://www.nrxpharma.com/expandedaccess/nrx-100.

About NRx Pharmaceuticals, Inc.

NRx Pharmaceuticals 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 recently filed an Abbreviated New Drug Application (ANDA) and initiated a New Drug Application filing for NRX-100 (IV ketamine) with an application for the Commissioner's National Priority Voucher Program for the treatment of suicidal depression.

The filing is based on results of well-controlled clinical trials conducted under the auspices of the US National Institutes of Health and the Government of France, licensed under a data sharing agreement.

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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