NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Announces Filing of Commissioner's National Priority Voucher Application for Intravenous Ketamine (NRX-100)

June 23, 2025

- Company has applied for new **Commissioner's National Priority Vouchers (CNPV)** for NRX-100. Continues to anticipate decisions on drug approval by year-end 2025
- Application under CNPV program is accretive to already-filed Abbreviated New Drug Application (ANDA) for preservative-free ketamine, with proprietary formulation under priority review request
- Company has received and complied with FDA information request for updated drug ingredient and label information on NRX-100
- Company has previously filed full Chemical Manufacturing and Controls (CMC) information for NRX-100 with FDA and has reported stability and sterility data sufficient to anticipate three-year room temperature shelf life for preservative-free ketamine

WILMINGTON, Del., June 23, 2025 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced filing for the newly-announced FDA Commissioner's National Priority Voucher program on behalf of NRX-100, its patent-pending, preservative-free formulation of ketamine for intravenous use.

On June 17, 2025, FDA Commissioner Marty Makary, MD, MPH announced a new approval pathway, the Commissioner's National Priority Voucher (CPNV)[1], for approval of drugs to enhance the health interests of Americans. Previously, on May 25 he identified psychedelic drugs for treatment of suicidal depression and PTSD as a national priority.[2] The new voucher may be redeemed by drug developers to participate in a Commissioner-led program that shortens its review time from approximately 10-12 months to 1-2 months following a sponsor's final drug application submission. The new CNPV process convenes experts from FDA offices for a team-based review rather than using the standard review system of a drug application being sent to numerous FDA offices.

The FDA plans, in the first year of the program, to give a limited number of vouchers to companies aligned with U.S. national priorities. In addition to receiving the benefits of this program, the agency may also grant an accelerated approval, if the product for which the voucher is used meets the applicable legal requirements for accelerated approval.

The FDA Commissioner will use specific criteria to make the vouchers available to companies that are aligned with the national health priorities of:

- Addressing a health crisis in the U.S.,
- Delivering more innovative cures for the American people,
- Addressing unmet public health needs, and
- Increasing domestic drug manufacturing as a national security issue.

To qualify for the CNPV, sponsors must submit the chemistry, manufacturing, controls (CMC) portion of the application and the draft labeling at least 60 days before submitting the final application. NRx has already submitted the CMC portion for NRX-100 and received FDA feedback (below).

The Company believes it meets each of the above criteria. Moreover, NRx has focused on innovative US high throughput manufacturing to replace a ketamine supply chain that frequently relies upon foreign sources and has added anti-diversion features to its product.

Suicidal depression and PTSD have been identified by the President of the United States and members of the Cabinet as a health crisis in the US. The FDA has already determined that NRX-100 addresses unmet public health needs through the award Fast Track Designation in combination with NRX-101. NRx Pharmaceuticals is manufacturing NRX-100 in West Columbia, SC.

NRx has received only one information request from FDA related to the CMC of NRX-100, in which FDA requested documentation related to the ketamine Active Pharmaceutical Ingredient and final proposed labeling language. NRx has complied with that information request.

"NRx is highly encouraged by the newly-announced Commissioner's National Priority Voucher Program, and believes that NRX-100 meets each of the criteria for acceptance," said Jonathan C. Javitt, MD, MPH, Chairman and CEO of NRx. "As previously determined by FDA, our products are innovative treatments that address the current health crisis of suicidal depression

and PTSD, and address an unmet medical need. We will be seeking New Drug Approval for NRX-100 in the treatment of suicidal depression and PTSD. The FDA's announcement has now validated our Company's focus on manufacturing and CMC by identifying CMC as a pre-requisite to the CNPV program. The timelines announced for the CNPV program are consistent with NRx's previous guidance of FDA decisions (PDUFA date) by year-end 2025. Our application under the CNPV program is accretive to the Abbreviated New Drug Application filed last week for preservative-free ketamine, for which we are seeking priority review."

Concurrent with the CNPV process, the Company is preparing a citizen petition to seek withdrawal of preservative-containing forms of ketamine, based on the toxicity associated with the benzethonium chloride preservative used in the historic formulation. The Company has also filed a patent on its preservative-free manufacturing process. Approval of either the citizen petition, or the patent, would be expected to enable the Company to gain market share in the current $750 million generic ketamine market that is forecast to reach $3-5 billion annually by 2033, in addition to a share of the market already established for ketamine products for treating depression.

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 bipolar depression, chronic pain, and PTSD. The Company is developing NRX-101, an FDA-designated investigational Breakthrough Therapy, for suicidal treatment-resistant bipolar depression. NRx plans to file an NDA for Accelerated Approval for NRX-101 in patients with bipolar depression and suicidality or akathisia. NRX-101 additionally has potential as a treatment for complicated UTI.

NRx recently filed an Abbreviated New Drug Application (ANDA) for NRX-100 (preservative free IV ketamine) for use in ketamine's currently approved indications. Additionally, the Company has initiated a New Drug Application filing for NRX-100 for the treatment of suicidal depression, based on results of well-controlled clinical trials conducted under the auspices of the US National Institutes of Health and newly obtained data from French health authorities, licensed under a data sharing agreement. NRx was awarded Fast Track Designation for development of ketamine (NRX-100) by the US FDA as part of a protocol to treat patients with acute suicidality and has filed a patent for this novel formulation with the US Patent and Trademark Office.

About HOPE Therapeutics, Inc.
HOPE Therapeutics, Inc. (www.hopetherapeutics.com), a subsidiary of NRx Pharmaceuticals, is a Healthcare delivery company that is building a best-in-class network of interventional psychiatry clinics to offer ketamine, transcranial magnetics stimulation (TMS), and other lifesaving therapies to patients with suicidal depression and related disorders, together with a digital therapeutic-enabled platform designed to augment and preserve the clinical benefit of NMDA-targeted drug therapy.

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. These statements include, among others, statements regarding the satisfaction of closing conditions necessary to consummate the acquisition of Kadima, Neurospa and Dura, and obtaining financing necessary to consummate the acquisitions. 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. 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, including, without limitation, whether the Company will receive the FDA's approval for its CNPV applications for NRX-100, whether the USPTO approves the Company's patent, whether the FDA will approve the Company's NDA to market and sell NRX-100, whether the Company will receive approval for its products by year-end 2025, and whether the USPTO will approve the Company's patent application. Any forward-looking statement reflects the Company's current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy, 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.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests

[2] https://www.biospace.com/fda/makary-backs-psychedelics-for-neuropsych-promises-speedy-review

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