NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Granted FDA Fast Track Designation for NRX-100 for Suicidal Ideation in Patients with Depression, including Bipolar Depression

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- *This designation expands the addressable population for NRX-100 to the 13 million Americans who consider suicide each year and represents a 10x expansion of the addressable population compared to the Designation granted in 2017 for bipolar depression alone*
- *The Designation includes an FDA determination that NRX-100 has the potential to address an unmet need, based on FDA's assessment of the data submitted*
- *Determination of "unmet need" is a requirement for a Commissioner's National Priority Voucher (CNPV) program.*
- *Suicide is a public health crisis. Approximately 13 million adults seriously consider suicide each year, according to the CDC, 3.7 million make a plan to commit suicide. An American dies from suicide every 11 minutes. Active-duty personnel, veterans, and first responders have a four-fold higher risk of suicide.*

WILMINGTON, Del., Aug. 11, 2025 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq:NRXP), a clinical-stage biopharmaceutical company, today announced US Food and Drug Administration (FDA) has granted Fast Track designation to NRX-100 for the treatment of suicidal ideation in patients with depression, including bipolar depression. This designation for NRX-100 as a standalone drug is a 10-fold expansion of the addressable population for NRX-100, compared to the designation granted in 2017 for NRX-100 in combination with NRX-101 (DCS/lurasidone) for treatment of Suicidal Bipolar Depression.

In granting the Fast Track designation, FDA made the determination that NRX-100 has the potential to address an unmet medical need, based on an assessment of the preliminary data contained in the Fast Track designation request. This determination of unmet medical need aligns with the eligibility requirements for the Commissioner's National Priority Voucher Program (CNPV)[i] and for the FDA's Accelerated Approval Program.[ii] The Company has applied for a CNPV, which has the potential to substantially shorten the review cycle for NRX-100.

Several well-controlled trials submitted to FDA in support of Fast Track Designation demonstrated a clinically meaningful and statistically significant reduction of suicidal ideation. In a Columbia University study licensed by NRx, suicidal patients treated with intravenous ketamine demonstrated a 55% response (i.e. 50% reduction in suicidality) compared to a 30% response to active comparator (P<.02).[iii] In a trial sponsored by the Government of France and licensed by NRx, 63% of patients achieved full remission from suicidal ideation in three days compared to 31% of those who received placebo (P<.001). This effect has not been proven with intranasal administration of ketamine.[iv]

"We thank FDA for its thoughtful review of our Fast Track designation request, and believe this regulatory determination is a significant step forward in our goal to address the national crisis of suicide among soldiers, first responders, veterans, and civilians alike." said Dr. Jonathan Javitt, Chairman and CEO of NRx Pharmaceuticals. "Large-scale government-supported trials have demonstrated a robust and statistically significant reduction in suicidal ideation and depression with administration of ketamine. This drug was also proven to be non-inferior to electroshock therapy in treating depression without the negative side effects of ECT. We look forward to working closely with the FDA in our quest to Bring Hope to Life."

Under the terms of the Fast Track program, NRx will be posting an expanded access policy for NRX-100 in the next two weeks and seeking a meeting with FDA leadership to finalize the data to be submitted under the Accelerated Approval / CNPV application. In addition to the benefits above, Fast Track Designation also grants enhanced communication with the FDA, as well as potential Priority Review and Rolling Review.

NRX-100 in Suicidal Ideation in Patients with Depression, Including Bipolar Depression

According to the CDC, approximately 13 million adults seriously consider suicide each year, 1.5 million attempt suicide, and an American dies from suicide every 11 minutes. NRX-100 – IV ketamine for suicidality in patients with depression, including bipolar depression – is designed to help address this national crisis.

NRx will be submitting patient-level data from controlled clinical trials that demonstrate ketamine to be superior to both a placebo and an active comparator, as well as either non-inferior or superior to electroshock therapy in treating various forms of depression, including patients with active suicidal ideation. Although ketamine in various forms is increasingly used to treat depression and related disorders, it is currently only approved by FDA only for use as an anesthetic and, therefore, not reimbursed by most insurance carriers for treatment of suicidality or depression. Intravenous ketamine is reimbursed by the Department of Veterans Affairs and the Department of Defense for its beneficiaries. By applying for FDA labeling for NRX-100 to treat suicidal depression, the Company hopes to make this potentially life-saving therapy available to all Americans, not just those who are able to pay out of pocket.

The 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. Having completed this Fast Track Designation, NRx is now filing draft labeling for NRX-100 to comply with the CNPV requirement.

NRX-100 is the first preservative-free presentation of ketamine to be filed with FDA. Currently available product, primarily of foreign manufacture, contains a known toxic preservative, Benzethonium Chloride (BZT) that is not Generally Recognized as Safe (GRAS) and is not allowed by FDA to be used in hand cleaners and topical antiseptics. NRx demonstrated long term stability and sterility with its patented preservative-free formulation of NRX-100. The Company has additionally filed a Citizen Petition seeking to have BZT removed from all intravenous ketamine products. The Company has instituted US-based high-volume manufacture of sterile, preservative-free ketamine.

Regarding Fast Track designation, FDA's website states:

A drug that receives Fast Track designation is eligible for some or all of the following:

- *More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval.*
- *More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers*
- *Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.*
- *Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.*

NRX-100 is poised to address the >$3 billion Suicidal Depression market in the US.

References

[i] https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program
[ii] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accelerated-approval-expedited-program-serious-conditions
[iii] Grunebaum, et al. Ketamine for rapid reduction of suicidal thoughts… Am J Psychiatry 2018;175:327-335.
[iv] Abbar, et al. Ketamine for the acute treatment of severe suicidal ideation… BMJ 2021;167:194-203

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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