HOPE Therapeutics, Inc. and NRx Pharmaceuticals, Inc. (Nasdaq:NRXP) Announce Alignment with FDA on Pediatric Study Plan for NRX-100 (ketamine)

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- FDA response highlights the importance of addressing suicidal depression in adolescents age 9-17
- Alignment on initial Pediatric Study Plan (iPSP) is a gating requirement for the upcoming filing of an NRX-100 New Drug Application (NDA) for suicidal depression
- NRx remains on track to file the NDA for NRX-100 in Q4 2024 with anticipated PDUFA date in Q2 2025

RADNOR, Pa., July 29, 2024 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical stage pharmaceutical company, today announced a communication from the US Food and Drug Administration (FDA) providing feedback and alignment on NRx's proposed initial Pediatric Study Plan (iPSP) for NRX-100 (ketamine) in the treatment of suicidal depression. Congress required the submission of an iPSP as a precondition to filing a New Drug Application in the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA).[1]

Suicide is a growing crisis among adolescents in the United States. According to the US Centers for Disease Control, 10% of high school students attempted suicide in the past year and 22% of high school students reported having seriously considered suicide. This percentage is highest among females (30%), American Indians/Alaska Natives (27%), and lesbian, gay, or bisexual teens (45%) (CDC, 2023). [2]

In support of its upcoming NDA filing, NRx will be submitting existing data supporting the safety and efficacy of ketamine to treat suicidal depression in adults. FDA has now documented its recognition that suicide is a serious and growing public health concern in adolescents as well. Based on the guidance received, NRx and HOPE Therapeutics will commit to conducting a clinical trial of NRX-100 in adolescents aged 9-17 with suicidal depression, but will not be required to study the effects of NRX-100 in younger age groups, following initial approval of NRX-100 in adults. Additional neurotoxicity studies will be conducted in juvenile animal subjects to support the safety of intravenous ketamine in this younger population.

"Youth suicide has reached crisis proportions in the United States with a 62% increase over the past two decades, disproportionately affecting minorities.[3] We appreciate FDA's recognition of the urgent unmet medical need related to suicidal depression in adolescents and look forward to expanding the mission of NRx and HOPE Therapeutics to serve America's youth in preventing needless deaths from suicidal depression, said Prof. Jonathan Javitt, Chairman of NRx Pharmaceuticals and Co-CEO of HOPE Therapeutics."

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 and chronic pain. 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 to act as a non-opioid treatment for chronic pain, as well as a treatment for complicated UTI.

NRx has recently announced plans to submit a New Drug Application for NRX-100 (IV ketamine) 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.

About HOPE Therapeutics, Inc.

HOPE Therapeutics, Inc. (www.hopetherapeutics.com) is a care delivery company developing a best-in-class network of clinics that currently offer ketamine 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 proposed public offering and the timing and the use of the proceeds from the offering. 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. 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 and 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.

[1] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Pediatric-Study-Plans--Content-of-and-Process-for-Submitting-Initial-Pediatric-Study-Plans-and-Amended-Pediatric-Study-Plans.pdf

[2] https://www.cdc.gov/healthyyouth/data/yrbs/pdf/YRBS_Data-Summary-Trends_Report2023_508.pdf

[3] https://www.apa.org/monitor/2023/07/psychologists-preventing-teen-suicide

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