NRx Pharmaceuticals Announces FDA Clearance of its Investigational New Drug (IND) Application for NRX-101 in the Treatment of Complicated Urinary Tract Infections

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- *"Study May Proceed" letter received from FDA*
- *Potential to initiate registrational study in 2024*

RADNOR, Pa., Dec. 18, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company today announced that its Investigational New Drug Application (IND) for the use of NRX-101, the company's patented combination of D-cycloserine and lurasidone, for the treatment of complicated Urinary Tract infections (cUTI), received clearance from the US FDA.

"Complicated Urinary Tract Infections afflict approximately 3 million Americans each year, and pathogens have become increasingly resistant to commonly used antibiotics. New treatment options are urgently needed" stated Jonathan Javitt, MD MPH, Founder and Chief Scientist of NRx Pharmaceuticals. "The D-cycloserine (DCS) component of NRX-101 is well known as an antibiotic and is excreted unmetabolized in the urine. However, the NMDA-antagonist effects of DCS led to its disuse in the United States, while it has remained a widely used anti-tuberculosis agent by the World Health Organization. NRx's patented discovery that combining DCS with small amounts of lurasidone counters the CNS side effects potentially and renders NRX-101 an important, patented antibiotic, just at a time when Americans are increasingly facing intravenous antibiotic therapy and even hospitalization and death from pathogens that were readily controlled a generation ago. This mission is personal to me, in that I have lost two close friends, one the father of a founding investor, to sepsis from urinary infections that were readily controlled a generation ago."

As previously disclosed, the company sees the greatest value for this program in an independent company dedicated to the development and commercialization of NRX-101 for cUTI. Because the manufacturing phase of NRX-101 is complete, the Company has secured Composition of Matter patent protection, and the Company has commercial-grade drug product on hand, this initiative is not expected to require additional investment in R&D prior to clinical trials. Accordingly, the company is developing plans to spin out a new company, much like the planned spin-out of Hope Therapeutics to develop NRX-100 (IV Ketamine) for suicidal depression, where NRx, existing shareholders (through a share dividend), and new investors will own the company.

cUTI Frequently Asked Questions **https://www.nrxpharma.com/nrx-pharmaceuticals-investigational-new-drug-ind-application-for-nrx-101-in-the-treatment-of-complicated-urinary-tract-infections/**

NRx has recruited Michael Manyak, MD, as Lead Clinical Advisor for this initiative. Prof. Manyak is an internationally-recognized urologist who trained at leading universities and the US National Institutes of Health. Most recently, he served as the Global Medical Affairs Director for the GlaxoSmithKline urology franchise and the Chief Medical Advisor for Crisis Response for Accenture. He is an Adjunct Professor of Urology and Engineering and former Professor of Immunology, Microbiology, and Tropical Medicine at The George Washington University (GWU). He is a member of the Baylor College of Medicine National School of Tropical Medicine.

"At a time when routine use of standard antibiotics demonstrates increasing resistance and failure to control urinary tract infections, I believe it is vital to advance safe, oral antibiotics for complicated UTI that have the potential to avoid the need for intravenous therapy, to keep patients out of the hospital, and to save lives," said Dr. Manyak. "I look forward to learning whether the efficacy we demonstrated for NRX-101 in the laboratory against some of the most resistant bacteria can be replicated in patients."

The company awaits the FDA's response to its request for Qualified Infectious Disease Product (QIDP) designation, expected next month.

About NRx Pharmaceuticals

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 has partnered with Alvogen Pharmaceuticals around the development and marketing of NRX-101 for the treatment of suicidal bipolar depression. NRX-101 additionally has potential to act as a non-opioid treatment for chronic pain.

NRx has recently announced plans to submit a New Drug Application for ketamine in 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.

Cautionary Note Regarding Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995, which may include, but are not limited to, statements regarding our financial outlook, product development, business prospects, and market and industry trends and conditions, as well as the Company's strategies, plans, objectives, and goals. These forward-looking statements are based on current beliefs, expectations, estimates, forecasts, and projections of, as well as assumptions made by, and information currently available to, the Company's management. Actual results could differ materially from those contemplated by the forward-looking statements. A discussion of these and other factors, including risks and uncertainties with respect to the Company, is set forth in the Company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K, as may be supplemented, or amended by the Company's Quarterly Reports on Form 10-Q. Given these risks, uncertainties, and factors, you are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by these cautionary statements.

The Company assumes no obligation to revise any forward-looking statement, whether as a result of new information, future events or otherwise. Accordingly, you should not place reliance on any forward-looking statement, and all forward-looking statements are herein qualified by reference to the cautionary statements set forth above.

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