NRx Pharmaceuticals and Nephron Pharmaceuticals Announce Joint Agreement to Develop Intravenous Ketamine to Treat Suicidal Depression

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- *No current FDA-approved formulation of ketamine for treatment of depression and suicidality*
- *Partners are developing a proprietary, tamper and diversion-resistant formulation and packaging*
- *Finished drug with two-year shelf stability targeted for November 2024, pending FDA approval*
- *Partners aim to submit New Drug Application by March 1, 2024*

RADNOR, Pa. and WEST COLUMBIA, S.C., Nov. 6, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", (NRx), a clinical-stage biopharmaceutical company and Nephron Pharmaceuticals, Inc. (Nephron), a leading manufacturer of sterile injectable drugs today announced the signing of a development and manufacturing agreement to manufacture a presentation of ketamine suitable for treating suicidal depression, an urgent public health need. Recent CDC data suggest that more than 3 million Americans have active thoughts of suicide and more than 50,000 die from suicide each year.

Ketamine has increasingly been recognized as valuable for rapid reduction of suicidal thoughts as part of a comprehensive program of care and its use in depression has been endorsed as standard of care by both the US Department of Defense and the Veterans Administration. However, no manufactured presentation of ketamine with been submitted to or approved by the US FDA for this purpose and caregivers rely on ad hoc compounding of ketamine, a practice that has been the topic of recent FDA warnings.

Submission of a New Drug Application for ketamine depends upon both the availability of data demonstrating safety and efficacy from well-controlled trials and upon the submission of data for a manufactured product demonstrating adherence to Good Manufacturing Practices and long term stability, among other requirements. These requirements are intended to be met via the NRx/Nephron partnership.

"We at NRx are excited to partner with Lou Kennedy and her team at Nephron and to avail ourselves of Nephron's decades of manufacturing excellence in developing a lifesaving product that has the potential to be available for patients by the end of 2024.," said Dr. Jonathan Javitt of Founder and Chief Scientist of NRx Pharmaceuticals. "We aim to combine Nephron's history of producing highly-regarded FDA-inspected products with data from well-controlled clinical trials in seeking approval from FDA and regulators around the world."

"There are few efforts as important as playing a role - through research and development - in tackling the nation's mental health crisis," said Lou Kennedy CEO and owner of Nephron Pharmaceuticals. "To this end, we are honored to partner with NRx Pharmaceuticals in a groundbreaking endeavor. Together, we are advancing the production of single-dose, intravenous Ketamine, which could be a crucial breakthrough for the treatment of depression. Not only are we addressing an immediate demand, but we are also laying the foundation for a potential New Drug Application, signifying a significant leap forward in the improvement of mental health outcomes for patients."

About NRx Pharmaceutical
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.

About Nephron Pharmaceuticals
A West Columbia, S.C.-based company, Nephron develops and produces safe, affordable sterile pharmaceutical products in a state of the art GMP-compliant manufacturing facility. The company also operates an industry-leading 503B Outsourcing Facility division which produces pre-filled sterile syringes, luer-lock vials, IV bottles and IV bags for hospitals across America, in an effort to alleviate drug shortage needs. For more information, please visit www.nephronpharm.com.

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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