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NRx Pharmaceuticals Announces First Successful Commercial Formulation for ZYESAMI™ (aviptadil), Enabling Volume Manufacture, Shipping, and Stockpiling of COVID-19 Medication Subject to Regulatory Approval

- NRx has Validated a Formulation, Manufacture, and Container Closure Method Suitable for High Volume Manufacture with Anticipated 1 year or greater stability

- New Manufacturing Method Designed According to Good Manufacturing Practices (GMP) Regulations as Implemented by US Food and Drug Administration, European Medicines Agency, and Other Regulatory Authorities

- New Formulation to be Implemented in Ongoing National Institutes of Health and I-SPY Clinical Trials and Emergency Use Programs as Allowed by Regional Authorities

RADNOR, Pa., July 22, 2021 /PRNewswire/ -- NRx Pharmaceuticals (NRx) (Nasdaq: NRXP) announced today it has validated the first commercial formulation of ZYESAMI™ (aviptadil) for intravenous use, allowing for high volume manufacture, with an anticipated one year or greater stability, under appropriate storage conditions. Simultaneously, NRx has achieved a 30-to-50-fold increase in its manufactured lot size of aviptadil, with a concurrent 90% reduction in the cost of its peptide supply. These two developments position NRx to potentially deliver millions of doses of ZYESAMI™ as potential regulatory approvals are obtained in various regions worldwide.

NRx Pharmaceuticals Announces First Successful Commercial Formulation for ZYESAMI™

"When we began developing aviptadil for treatment of COVID-19, we discovered that the original RLF-100 formulation and manufacturing method had only a few weeks of stability, leaving hospitals unable to stock the investigational medicine in pharmacies, and leaving aviptadil out of consideration for national strategic stockpiles. Moreover, the high cost of peptide and an inability to manufacture more than 100 grams a month limited the commercial utility of aviptadil," said Prof Jonathan Javitt, MD, MPH, Chairman and CEO of NRx. "We have now turned the corner and can produce both the aviptadil peptide and finished medicine in million dose quantities. We have also developed and validated the first modern chromatography assays required to ensure the purity and stability of the drug product. The new formulation method and high-speed manufacturing process adapts to the fragile nature of vasoactive intestinal peptide."

As the Delta variant and more threatening, newer mutations of the Coronavirus continue to erode the immunity created by first-generation vaccines, NRx is in active discussion with national health ministries and regulators regarding Emergency Use Authorization for ZYESAMI™ (aviptadil). The new formulation allows for the immediate shipping worldwide, upon potential EUA approval.

"Twenty years ago, Dr. Sami Said formulated the first doses of aviptadil by hand in a hospital pharmacy," said Dr. Riccardo Panicucci, a top scientific advisor to NRx. "We began this project a year ago, with 9 days of stability and an ability to manufacture about 100 doses of medicine each day. We learned through significant study and testing that the important biologic activity of this small peptide is accompanied by a fragile molecular structure that is destroyed by standard high-volume pharmaceutical manufacturing processes. Fortunately, we and our

manufacturing partners have reached a greater level of commercial manufacturing, just as the pandemic seems poised to enter a new wave."

The successful new formulation and manufacturing scaleup of ZYESAMI™ allows NRx to relaunch its Expanded Access and Right to Try programs as it continues to seek Emergency Use Authorization in the United States. These programs are designed to afford patients at highest risk of death from COVID-19, and who have no other therapeutic options, the ability to access ZYESAMI™ on an investigational basis.

About NRx Pharmaceuticals
NRx Pharmaceuticals (www.nrxpharma.com) (NRx) draws upon more than 300 years of collective, scientific and drug-development experience to bring improved health to patients. Its investigational product, ZYESAMI™ (aviptadil) for patients with COVID-19, has been granted Fast Track designation by the US Food and Drug Administration (FDA) and is currently undergoing phase 3 trials funded by the US National Institutes of Health, the Biomedical Advanced Research and Development Authority part of the US Department of Health and Human Services, and the Medical Countermeasures program, part of the US Department of Defense. The FDA has additionally granted Breakthrough Therapy Designation, a Special Protocol Agreement, and a Biomarker Letter of Support to NRx for NRX-101, an investigational medicine to treat suicidal bipolar depression. NRX-101 is currently in Phase 3 trials, with readouts expected in 2022.

NRx is led by executives who have held senior roles at Allergan, J&J, Lilly, Novartis, Pfizer, and the US FDA. NRx is chaired by Jonathan Javitt, MD, MPH, an Adjunct Professor at the Johns Hopkins School of Medicine, who also serves as a Senior Fellow in the National Security Health Policy Center of the Potomac Institute for Policy Studies. In addition to 30 years of experience in drug development, Dr. Javitt has been appointed to leadership roles under Presidents Reagan, Bush ('41), Clinton, and Bush ('43), where he served as a Special Employee of the Undersecretary of Defense. The NRx board includes Dr. Sherry Glied, former US Assistant Secretary for Health (ASPE), Daniel E. Troy, JD, former Chief Counsel of the US FDA, Chaim Hurvitz, former director of Teva and President of the Teva International Group, and General HR McMaster, Ph.D. (US Army, Ret.) the 26th United States National Security Advisor. NRx is publicly traded on the Nasdaq Global Select Exchange under the stock ticker NRXP.

Cautionary Note Regarding Forward-Looking Statements
This announcement of NRx Pharmaceuticals 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.

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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