October 12, 2021

NRx Pharmaceuticals Announces Progress on Worldwide Commercial Scale Development of ZYESAMI™ (aviptadil)

RADNOR, Pa., Oct. 12, 2021 /PRNewswire/ -- NRx Pharmaceuticals (Nasdaq: NRXP), today announced that a revised Investigational New Drug module on the manufacturing of ZYESAMI™ (aviptadil) was submitted to the US Food and Drug Administration (FDA), containing documentation that confirmed Nephron Pharmaceuticals, Inc. is prepared to supply ZYESAMI on a commercial scale. This module will now be used as part of the FDA's rolling review process supporting the New Drug Application for ZYESAMI.

As thousands of people around the world continue to die each day from COVID-19, we are continuing our efforts to ensure that NRx has the supply and logistics in place to provide ZYESAMI to patients where it is granted regulatory approval," said Prof Jonathan Javitt, MD, MPH, CEO and Chairman of NRx.

NRx has also received notification that a European QP (Qualified Person) Auditor has completed an inspection at a separate manufacturing facility with no adverse findings. NRx awaits a QP Declaration that is required by the EU regulatory authorities for the release of ZYESAMI. The audit was completed in preparation for submission of European Union (EU)-standard ZYESAMI to EU and United Kingdom health regulatory authorities. Under EU law, a QP Auditor is responsible for certifying that each batch of a medicinal product meets all required provisions when released from a manufacturing facility within the EU or imported into the EU.

"As thousands of people around the world continue to die each day from COVID-19, we are continuing our efforts to ensure that NRx has the supply and logistics in place to provide ZYESAMI to patients where it is granted regulatory approval," said Prof Jonathan Javitt, MD, MPH, CEO and Chairman of NRx.

About ZYESAMI™/VIP in COVID-19

Aviptadil is a synthetic form of Vasoactive Intestinal Polypeptide (VIP), first discovered by the late Prof. Sami Said in 1970, and ZYESAMI™ is named in his honor. Although primarily concentrated in the lung, it was first purified from the intestinal tract. VIP binds specifically to the alveolar type II cell (ATII) in the air sac (alveolus) of the lung, where it has been shown to have potent anti-inflammatory/anti-cytokine activity in animal models of respiratory distress, acute lung injury, and inflammation. Most importantly, VIP stimulates ATII cells to make the surfactant that must coat the lining of the lungs in order for them to exchange oxygen with the blood. Loss of surfactant causes respiratory failure and alveolar collapse, which are hallmarks of COVID-19.

COVID-19-related respiratory failure is caused by selective infection of the ATII cell by the SARS-CoV-2 virus. The ATII cells are vulnerable because of their (ACE2) surface receptors, which serve as the route of entry for the virus. Coronavirus infection of the ATII cell shuts down surfactant production, triggers the formation of inflammatory cytokines, and causes cell death (cytopathy). VIP is shown to upregulate surfactant production, block Coronavirus replication in the ATII cell, block cytokine synthesis, and prevent viral-induced cell death (cytopathy). Other than ZYESAMI™, no currently proposed treatments for COVID-19 specifically target this mechanism of action.

About NRx Pharmaceuticals

NRx Pharmaceuticals (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. In July 2021, the Government of Israel awarded NRx the exclusive worldwide right to develop and market the BriLife™ COVID vaccine developed by the Israel Institute for Biological Research.

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 Prof Jonathan Javitt, MD, MPH, who has held leadership roles in six biotechnology startup companies with public exits and been appointed to advisory roles in four US Presidential Administrations. 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 H.R. McMaster, Ph.D. (US Army, Ret.) the 26th United States National Security Advisor.

Cautionary Note Regarding Forward-Looking Statements
This announcement of NRx Pharmaceuticals, Inc. includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the US 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

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Released October 12, 2021

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