# NRx Pharmaceuticals Announces New Finding from ZYESAMI™ (aviptadil) Phase 2b/3 Clinical Trial Demonstrating Clinically Significant Relief from Respiratory Distress in Critical COVID-19

August 30, 2021

**- NRx Has Provided Updated Data to US Food and Drug Administration (FDA) in Support of Emergency Use Authorization Request for ZYESAMI™ (aviptadil)**

**- NRx to Submit Breakthrough Therapy Designation to FDA for ZYESAMI™ for the Treatment of Respiratory Failure in Patients with Critical COVID-19**

RADNOR, Pa., Aug. 30, 2021 /PRNewswire/ -- NRx Pharmaceuticals (NRx) (Nasdaq: NRXP) announced an additional finding in its phase 2b/3 clinical trial investigating ZYESAMI™ (aviptadil) for the treatment of patients with acute Respiratory Failure due to Critical COVID-19. Previously announced results have focused on survival and recovery from respiratory failure at 60 days, and ZYESAMI's apparent role in preventing rise in the inflammatory cytokine IL-6, known as "Cytokine Storm."

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NRx's new analysis shows that patients treated with ZYESAMI demonstrated improvement in blood oxygen, indicative of improved lung function, within a day of starting treatment. The average difference in Respiratory Distress Ratio between those treated with aviptadil and placebo was both clinically meaningful and statistically significant. Moreover, the difference is comparable to that reported a year ago from an open label study at Houston Methodist Hospital by Dr. J Georges Yousef.

"With the conclusion of the analysis of primary and secondary endpoints, we are able to focus on prespecified endpoints that confirm mechanism of action," said Prof Jonathan Javitt, MD, MPH, Chairman and CEO of NRx. "COVID-19 attacks the cells that line the lung in a manner that prevents them from transmitting oxygen to the body. It is this respiratory failure that starts the lethal process of COVID," This latest analysis provides confirmatory evidence that aviptadil improves the lung's ability to transmit oxygen within a day of initiating treatment. The benefit was seen across all patients, all baseline severities, and all types of hospitals. We believe this new finding illustrates ZYESAMI's mechanism of action in a placebo-controlled trial and supports our application for Breakthrough Therapy Designation to the FDA."

Prior data regarding reduced respiratory distress were reported by Dr. J. Georges Youssef, Head of Academic Pulmonary Medicine at Houston Methodist Hospital one year ago. Dr. Youssef and colleagues reported the results in 21 patients treated with ZYESAMI, compared to 24 patients who received best-available standard of care.

This latest analysis also supports NRx's application for Breakthrough Therapy Designation (BTD) to the FDA for ZYESAMI. BTD is a process designed to expedite the development and review of medicines intended to treat a serious condition and is supported by preliminary clinical evidence showing the drug may demonstrate substantial improvement over available therapies on a clinically significant endpoint(s). https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy

About ZYESAMI™/VIP in COVID-19

ZYESAMI (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 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.

About NRx Pharmaceuticals

NRx Pharmaceuticals (www.nrxpharma.com) 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, a 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 currently has the BriLife for COVID-19 in phase 3 trials, and holds the exclusive worldwide license to commercialize the vaccine. The BriLife vaccine was first 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 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.

CORPORATE CONTACT

INVESTOR RELATIONS

Jack Hirschfield
Head of External Affairs, NRx
jhirschfield@nrxpharma.com
512-674-5163

John Mullaly
LifeSci Advisors
jmullaly@lifesciadvisors.com
617-429-3548

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