



NRx Pharmaceuticals Announces Improved Survival at One Year in Highly Comorbid COVID-19 Patients Treated with ZYESAMI (aviptadil)

- ZYESAMI™ (aviptadil) Has Previously Demonstrated a Statistically Significant Increase in Survival of Highly Comorbid COVID-19 Patients in Two 60-day Trials

- In a Study of Highly Comorbid Patients, ZYESAMI Provided a Threefold, Statistically Significant Increase in Likelihood of Survival at One Year

RADNOR, Pa., Sept. 27, 2021 /[PRNewswire](#)/ -- NRx Pharmaceuticals (Nasdaq: NRXP), a clinical stage, biopharmaceutical company, today announced top line data demonstrating improved outcomes at one year in highly comorbid patients with COVID-19 who were treated with ZYESAMI™.

"These latest data are encouraging and will help those of us on the frontlines treat the sickest COVID patients, potentially providing new treatment options and strategies," said Dr. J. Georges Youssef. Between June and September 2020, a trial was conducted at a leading tertiary care hospital involving patients with Critical COVID-19 whose level of comorbidity excluded them from the randomized phase 2b/3 clinical trial of ZYESAMI. A statistically significant difference in both survival and recovery from respiratory failure was reported at 28 days. Those findings are soon to be published in a peer-reviewed journal.

Participants in this trial have now been followed for one year from initial enrollment. Top-line results show a statistically significant ($P < .0001$) 3-fold advantage in likelihood of being alive at one year post treatment (60% vs. 20%) among those treated with ZYESAMI, in addition to standard of care, compared to those who received the standard of care alone. Assignment to ZYESAMI in the trial was based on the specific medical team which admitted the patient to the intensive care unit (ICU). Once in the ICU, all patients were cared for by the same medical team, and according to the same treatment protocols.

"We are still learning so much about COVID-19, especially in patients already managing chronic medical conditions, and continuing to recover from COVID-19" said Dr. J. Georges Youssef, the Principal Investigator who serves as Head of Academic Pulmonary Medicine at Houston Methodist Hospital and as Assistant Professor of Clinical Medicine at Weill Cornell Medical College. "These latest data are encouraging and will help those of us on the frontlines treat the sickest COVID patients, potentially providing new treatment options and strategies."

These one-year findings are consistent with the increased odds of 60-day survival seen in the previously reported [results](#) from the phase 2b/3 randomized controlled trial of ZYESAMI. ZYESAMI Remains Under Review by the US Food and Drug Administration for Emergency Use Authorization in Patients Suffering Critical Covid-19 with Respiratory Failure.

About ZYESAMI™ (aviptadil)/VIP in COVID-19

ZYESAMI (aviptadil) is a synthetic form of Vasoactive Intestinal Polypeptide (VIP). Aviptadil binds specifically to the alveolar type II cell (AT2) in the air sac (alveolus) of the lung, where it has demonstrated potent anti-

inflammatory/anti-cytokine activity in animal models of respiratory distress, acute lung injury and inflammation. Aviptadil stimulates AT2 cells to produce the surfactant that coats the lining of the lungs to facilitate oxygen exchange with 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 AT2 cells are vulnerable because of their (ACE2) surface receptors, which serve as the route of entry for the virus. Coronavirus infection of the AT2 cell shuts down surfactant production, triggers the formation of inflammatory cytokines, and causes cell death (cytopathy). Aviptadil is shown to upregulate surfactant production, block Coronavirus replication in the AT2 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 (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 also has the BriLife™ vaccine for COVID-19 in clinical 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.

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Released September 27, 2021

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