November 29, 2021

NRx Pharmaceuticals Identifies Significantly Higher Likelihood of Surviving and Recovering from Critical COVID-19 in ZYESAMI® (aviptadil) Treated Patients Previously Administered Remdesivir

•Analysis was conducted in the subgroup of ZYESAMI- and placebo-treated patients who were previously treated with remdesivir in the COVID-AIV trial representing approximately 70 percent of the study population
•Analysis was conducted in response to US Food and Drug Administration (FDA) request for additional clinical data on effect of ZYESAMI compared to currently-approved therapy including remdesivir
•NRx to submit new analysis and safety data to the FDA in support of Emergency Use Authorization and Breakthrough Therapy Designation Requests
•US National Institutes of Health-sponsored trial to compare effects of ZYESAMI and remdesivir individually and in combination continues to enroll patients

RADNOR, Pa., Nov. 29, 2021 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals (Nasdaq: NRXP) announced today that it has completed an analysis to identify clinical evidence that indicates a substantial improvement after treatment with ZYESAMI® (aviptadil) in patients with Critical COVID-19 and Respiratory Failure over existing therapies such as remdesivir. NRx asked Prof. David Schoenfeld, one of the world's most widely published statisticians with unique expertise in life-threatening diseases of the lung to conduct the analysis.

Dr. Schoenfeld analyzed the subgroup of patients in the COVID-AIV trial (NCT 04311697) that remained in respiratory failure despite treatment with remdesivir. The analysis identified a statistically-significant (P=.03) 2.5 fold increased odds of being alive and free of respiratory failure at 60 days (the primary endpoint) and a statistically significant (P=.006) four-fold higher odds of being alive at day 60 among patients treated with aviptadil compared to those treated with placebo.

Baseline treatment with remdesivir was prespecified as a covariate in the protocol agreed to with the US Food and Drug Administration (FDA) prior to initiation of the trial and remdesivir did not show any independent survival or recovery advantage in the subgroup. Analysis of the remdesivir-treated subgroup was a post-hoc analysis performed in response to the FDA's request for additional clinical evidence that aviptadil may demonstrate a substantial improvement over existing therapies.

The reanalysis of the clinical trial data additionally confirmed a statistically-significant (P=.03) two-fold survival advantage seen across all patients treated with aviptadil compared to those treated with placebo and demonstrated an increased odds of reaching the primary endpoint in the study, being both alive and free of respiratory failure at 60 days that approached statistical significance (P=.08).

The FDA recently declined Emergency Use Authorization (EUA) and Breakthrough Therapy Designation (BTD) for ZYESAMI and invited a new request based on new clinical evidence that aviptadil may demonstrate a significant improvement in treatment over existing therapies. Based on FDA's input, NRx has narrowed its requested BTD indication to "Treatment of COVID-19 Respiratory Failure in patients who progress despite treatment with remdesivir and other approved therapies."

Dr. Schoenfeld's report concludes, "The study provides preliminary evidence that aviptadil is effective in increasing the odds of recovery and survival from respiratory failure among the sickest COVID patients overall

and particularly in those whose respiratory failure has progressed despite treatment with remdesivir. The study shows a significant increase in the likelihood that patients will recover and leave the ICU and a four-fold increase in the odds of survival after treatment with aviptadil compared to placebo, among the 127 patients who remained in respiratory failure despite treatment with remdesivir."

"We appreciate Dr. Schoenfeld's wisdom and insight based on his vast experience with studies of Acute Respiratory Distress, such as ours," said Prof. Jonathan Javitt, MD, MPH, CEO and Chairman of NRx Pharmaceuticals. "The definitive findings on our medicine will come from the global trial currently being conducted by the NIH, which is more than halfway enrolled. However, at a time when COVID deaths are surging, we hope that the FDA will consider these new clinical findings in patients who have exhausted currently-approved therapies."

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. The Company is developing the BriLife® Covid vaccine, developed by the Israel Institute for Biological Research, under an exclusive license from the Israel Ministry of Defense. NRx is additionally developing ZYESAMI® (aviptadil) for patients with COVID-19, and 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 (BARDA) 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 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.

About Prof. David Schoenfeld

David Alan Schoenfeld, PhD, is a Professor (emeritus) of Medicine at Harvard Medical School and was Professor of Public Health at the Harvard TH Chan School of Public Health. He founded the statistics unit at the Harvard Mass General Hospital and 1996 and served for 15 years as the Principal Investigator for the Clinical Coordinating Center of the Acute Respiratory Distress (ARDS) Network. He has served as a member of an FDA advisory committee and two major International Data Safety and Monitoring Committees. Dr. Schoenfeld has authored more than 390 peer-reviewed publications and is ranked as one of the world's most widely cited statisticians and scientists.

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 statements set forth above.

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Source: NRx Pharmaceuticals, Inc.

Released November 29, 2021

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