



NRx Pharmaceuticals Announces Favorable, New Safety Report for ZYESAMI® (aviptadil) in NIH Sponsored ACTIV-3b Critical Care Study in Patients with Life-Threatening COVID-19

- After Review of More than 300 Enrolled Patients in ACTIV-3b Critical Care Study, No New Safety Concerns Raised by Independent Data Safety Monitoring Board; Study Cleared to Continue Enrollment to Target 640 Patients**
- ACTIV-3b Critical Care Study is Evaluating ZYESAMI® (aviptadil) and Remdesivir, in Critical COVID-19 Patients, as Monotherapy and in Combination Against Placebo**
- ACTIV-3b Critical Care is a Public-Private Partnership Sponsored by the US National Institutes of Health to Treat COVID-19**

RADNOR, Pa., Nov. 2, 2021 /[PRNewswire](#)/ -- NRx Pharmaceuticals (NASDAQ: NRXP), a clinical-stage, biopharmaceutical company, today provided a new safety update on ZYESAMI® (aviptadil), which is being tested in the ACTIV-3b Critical Care Phase 3 study sponsored by the National Institutes of Health. In its third scheduled analysis, the study's Independent Data Safety Monitoring Board found no new safety concerns after reviewing a total of more than 300 patients and recommended continued enrollment.

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"This safety analysis by the NIH continues to contribute evidence that ZYESAMI is safe to administer to patients with Critical COVID-19, who have no other therapeutic alternative," said Prof. Jonathan Javitt, MD, MPH, Chairman and CEO of NRx. "We now have safety data on nearly 600 patients treated with ZYESAMI in the ICU or step-down unit, with no reports of unexpected, drug-related, serious adverse events."

ACTIV-3b is a randomized, placebo-controlled clinical trial testing ZYESAMI and remdesivir (Veklury) -- alone and in combination -- in hospitalized patients with acute respiratory failure due to COVID-19 who require high-flow supplemental oxygen delivered by nasal cannula, mechanical ventilation, or extracorporeal membrane oxygenation.

On May 31, 2021, NRx submitted a request for Emergency Use Authorization to the US Food and Drug Administration (FDA) for ZYESAMI for the treatment of patients suffering from Critical Covid-19 with respiratory failure. That request remains pending.

ACTIV-3b represents one of three ongoing studies of ZYESAMI in Severe or Critical COVID-19.

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 statements set forth above.

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