



NRx Pharmaceuticals Announces Positive Safety Report for ZYESAMI™ (aviptadil) in NIH Sponsored ACTIV-3 Critical Care Study in Patients with Life-Threatening COVID-19

- After Review of Approximately 140 patients in ACTIV-3 Critical Care Study, No New Safety Concerns Raised by Independent Data Safety Monitoring Board, Study to Continue Enrollment to Target More than 600 Patients**
- ACTIV-3 Critical Care is a Public-Private Partnership Sponsored by the US National Institutes of Health to Treat COVID-19**
- ACTIV-3 Critical Care is Evaluating ZYESAMI™ and Remdesivir, in Critical COVID-19 Patients, as Monotherapy and in Combination Against Placebo**

RADNOR, Pa., Aug. 18, 2021 /[PRNewswire](#)/ -- NRx Pharmaceuticals (NRx) (NASDAQ: NRXP), a clinical stage, biopharmaceutical company today provided a safety update on ZYESAMI™ (aviptadil) which is being tested in the ACTIV-3 Critical Care Phase 3 study sponsored by the National Institutes of Health. The study's Data Safety Monitoring Board found no new safety concerns in the trial and recommended continued enrollment.

<div>After Review of Approximately 140 patients, No New Safety Concerns Raised by Independent Data Safety Monitoring Board</div>	<div>ACTIV-3 is a randomized, blinded, placebo-controlled clinical trial testing ZYESAMI™ and the antiviral remdesivir (Veklury) 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.</div> <div>Study investigators are randomizing patients to receive one of four treatment regimens in addition to standard of care: both ZYESAMI™ and remdesivir, ZYESAMI™ and a placebo, remdesivir and placebo, or only placebo. ZYESAMI™ is administered as a daily 12 hour intravenous infusion over three days. Those randomized to receive remdesivir will receive it for up to 10 days via intravenous infusion.</div>
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ZYESAMI™ (aviptadil) is a proprietary, synthetic version of Vasoactive Intestinal Peptide or VIP, which is made naturally in the human body and appears to have lung-protective, anti-viral and anti-inflammatory effects.

ACTIV-3 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 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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