



## NRx Pharmaceuticals Presents Evidence ZYESAMI™ (aviptadil) Helps Prevent "Cytokine Storm" in Patients with COVID-19

July 19, 2021

- Sudden Rise in Inflammatory Cytokines (IL-6) Associated with Death in COVID-19 and Other Forms of Acute Respiratory Distress Syndrome
- Data from Randomized Phase 2b/3 Trial Shows Patients Treated with ZYESAMI™ are Significantly Less Likely to Experience IL-6 Cytokine Rise, and Have Improved Survival and Recovery from Respiratory Failure, Compared to Patients Receiving Placebo
- Data Have Been Submitted to US Food and Drug Administration (FDA) as Part of the Emergency Use Authorization (EUA) Application for ZYESAMI™
- NRx Submitting Biomarker Letter of Intent to FDA Based on Phase 2b/3 Data in Support of ZYESAMI™ EUA Application and Future Potential Indications

RADNOR, Pa., July 19, 2021 /PRNewswire/ -- NRx Pharmaceuticals (Nasdaq: NRXP), will present data at the Disease Control and Prevention Summit on July 21, 2021 at 10:10 EST, via the following link: [https://www.terrapinn.com/template/live/landing/a0A4G00001ZmpzpUAB/10433?utm\\_source=&utm\\_medium=landing-page&utm\\_campaign=-referral&utm\\_term=referral-marketing&utm\\_content=PA03744357](https://www.terrapinn.com/template/live/landing/a0A4G00001ZmpzpUAB/10433?utm_source=&utm_medium=landing-page&utm_campaign=-referral&utm_term=referral-marketing&utm_content=PA03744357)

---

NRx Pharmaceuticals Presents  
Evidence ZYESAMI™ (aviptadil)  
Helps Prevent "Cytokine Storm" in  
Patients with COVID-19

---

The presentation identifies a statistically significant effect of ZYESAMI™ (aviptadil) in preventing the sharp rise in cytokines, commonly associated with mortality in patients with COVID-19. In the recently-completed phase 2b/3 trial, patients treated with placebo experienced a statistically significant elevation in interleukin 6 (IL-6) cytokine levels, whereas those treated with ZYESAMI™ had a minimal increase in IL-6. Change in

cytokine level was a prespecified endpoint of the study.

Health regulators continue to prioritize therapies for COVID-19 which help block the impact of IL-6 cytokines in patients with COVID-19. The anti-cytokine effect of ZYESAMI™ was additionally associated with a significant decrease in 60-day mortality.

The cytokine data were collected as part of the phase 2b/3 trial of ZYESAMI™ (aviptadil) compared to placebo, in critically ill patients with COVID-19 respiratory failure. The effect was noted across a diverse set of patients, suffering different levels of COVID-19 severity and treated in both tertiary care and community hospitals.

NRx has submitted these findings to the US Food and Drug Administration (FDA) as a supplement to its pending application for Emergency Use Authorization, (EUA) and is submitting a biomarker letter of intent to the FDA as part of its biomarker program, authorized under the 21st Century Cures Act.

"At a time when hospital admissions for COVID are rising worldwide, these placebo-controlled biomarker data suggest that aviptadil may play a critical role in preventing the sudden elevation of cytokines that is associated with mortality," said Prof Jonathan Javitt, MD, MPH, Chairman and CEO of NRx. "This linkage between the clinical effect of aviptadil on survival and recovery and a measurable biologic change in cytokine levels provides a basis for seeking a biomarker-based regulatory path as envisioned by the 21st Century Cures Act. The lethal impact of "cytokine storm" is associated with mortality in a variety of lethal conditions including Acute Respiratory Distress Syndrome, a common cause of death in sepsis, and amniotic fluid embolus, a primary cause of maternal death during pregnancy."

NRx continues to respond to FDA information requests for additional data in support of the currently pending EUA application for ZYESAMI™ in treating critically-ill patients with COVID-19.

### About NRx Pharmaceuticals

NRx Pharmaceuticals ([www.nrxpharma.com](http://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 is led by executives who have held senior roles at Allergan, J&J, Lilly, Novartis, Pfizer, and the US FDA. The NRx board

includes Dr. Sherry Glied, former US Assistant Secretary for Health, Daniel E. Troy, former Chief Counsel of the US FDA, Chaim Hurvitz, former director of Teva and President of the Teva International Group, and General HR McMaster, PhD (US Army, Ret.) the 26th United States National Security Advisor. NRx is publicly traded on the Nasdaq Global Select Exchange under the stock ticker NRXP.

#### 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:

Jack Hirschfield  
Head of External Affairs  
NRx,  
[jhirschfield@nrxpharma.com](mailto:jhirschfield@nrxpharma.com)  
512-674-5163

INVESTOR RELATIONS,  
John Mullaly  
LifeSci Advisors  
617-429-3548  
[jmullaly@lifesciadvisors.com](mailto:jmullaly@lifesciadvisors.com)

View original content to download multimedia: <https://www.prnewswire.com/news-releases/nrx-pharmaceuticals-presents-evidence-zyesami-aviptadil-helps-prevent-cytokine-storm-in-patients-with-covid-19-301336297.html>

Cision

SOURCE NRx Pharmaceuticals