



NRx Pharmaceuticals Announces Expansion of ZYESAMI® (aviptadil) US Expanded Access and Right to Try Programs for Patients with COVID-19 Respiratory Failure who have Exhausted All Approved Treatments

January 18, 2022

- ZYESAMI® (aviptadil) is currently in a Phase 3 clinical trial being conducted by the National Institutes of Health (NIH)**
- NRx will continue to provide ZYESAMI to hospitals enrolled in NRx's Expanded Access Protocol under US Food and Drug Administration guidelines**
- NRx is also making ZYESAMI available as an investigational medicine under the Federal Right to Try Act**
- ZYESAMI is available to patients who have progressed despite treatment with remdesivir and other approved medicines and who are not able to participate in the NIH trial**
- NRx manufacturing program now supports increases in demand under Expanded Access and Federal Right to Try programs**

RADNOR, Pa., Jan. 18, 2022 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals (Nasdaq: NRXP) today announced enhancements to its Expanded Access and Right to Try programs. The programs enable patients with respiratory failure from COVID-19, who have tried all approved medicines, including remdesivir, and who are not able to participate in a clinical study, to receive ZYESAMI® (aviptadil) upon a physician's prescription.

This expansion comes as supplies of ZYESAMI have increased through the partnership between NRx and Nephron Pharmaceuticals, which is manufacturing ZYESAMI at commercial scale. The expanded production will also support the ongoing ACTIV-3b trial conducted by the National Institutes of Health (NIH) both in the US and Brazil.

ZYESAMI is a long-term stable form of vasoactive intestinal peptide, which was previously shown in clinical trials to be associated with a two-fold increased odds of survival at 60 days. The subgroup of patients who were treated with ZYESAMI after remdesivir and other approved therapies demonstrated a 2.8-fold increased odds of recovering from respiratory failure by day 28 ($P=.03$), which was sustained to day 60, together with a four-fold increased odds of surviving to day 60 ($P=.006$). Adverse events included principally diarrhea (33% aviptadil vs 1.5% placebo) and hypotension (26% aviptadil vs 22% placebo) of patients. Detailed data on results seen in clinical trials of ZYESAMI® (Aviptadil) may be viewed on the NRx website (<https://www.nrxpharma.com/right-to-try/>). ZYESAMI remains an investigational medicine that is not approved by the US FDA.



The NIH is currently studying ZYESAMI as part of its ACTIV-3b (TESICO) trial (<https://clinicaltrials.gov/ct2/show/NCT04843761>), which has enrolled approximately two-thirds of patients and has not identified unexpected safety concerns.

Hospitals that enroll in the FDA-supervised Expanded Access Program (EAP) are able to store ZYESAMI on-site and provide it to patients without delay.

Patients who are hospitalized at facilities not enrolled in the EAP program may be treated under the Federal Right to Try Act, which does require an application to NRx by a licensed, accredited critical care physician and review by the Company's medical team.

"Given the urgency caused by the Omicron surge, we have worked with our manufacturing partner to increase production to a level that supports expanded access to our investigational medicine ZYESAMI, potentially at all US hospitals. We will continue to increase production to meet demand in order to offer one last option to patients who have exhausted all currently approved therapies," said Prof. Jonathan C. Javitt, MD, MPH, CEO and Chairman of NRx Pharmaceuticals.

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.

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.

CORPORATE CONTACT:

Jack Hirschfield – Head of Corporate Communications, NRx
jhirschfield@nrxpharma.com

INVESTOR RELATIONS

Eric Goldstein
Managing Director – LifeSci Advisors
egoldstein@lifesciadvisors.com

1 <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try>

Source: NRx Pharmaceuticals, Inc.