NRx Pharmaceuticals Receives US Food and Drug Administration Review of ZYESAMI® (aviptadil) Manufacturing Information

November 11, 2021

•US Food and Drug Administration Review Allows for High Volume Production of ZYESAMI® (aviptadil)
•Shelf Life of ZYESAMI Now Extended from 62 Days to 150 Days

RADNOR, Pa., Nov. 11, 2021 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals (NASDAQ: NRXP), today announced receipt of the US Food and Drug Administration's (FDA) response to NRx's October 8 submission of updated manufacturing information for ZYESAMI® (aviptadil).

The completion of this review, without the imposition of any clinical hold by the FDA, enables NRx to distribute ZYESAMI, produced at commercial scale, under Good Manufacturing Practices (GMP) for clinical trials and other future purposes approved in future regulatory actions. NRx looks forward to working with the FDA to complete the chemistry, manufacturing, and controls (CMC) review that will ultimately be required for any potential drug approval.

Prior to the COVID pandemic, ZYESAMI was never manufactured as a commercial drug for intravenous use. Between March and May 2020, NRx formulated aviptadil based on historical files and initiated an FDA-approved, phase 2b/3 clinical trial by producing ZYESAMI in an FDA-inspected 503b pharmacy.

Until now, ZYESAMI was manufactured for clinical trials purposes in handmade, 300 dose batches, with a limited shelf life of 62 days. The FDA has now reviewed a GMP manufacturing process at a batch size of 10,000 – 100,000 doses with a current shelf life of 150 days and identified no basis for a clinical hold.

"This represents the first time aviptadil has been manufactured in an FDA-inspected commercial GMP environment for intravenous and inhaled use and passed regulatory review of manufacturing and CMC. With the help of our partners at Nephron Pharmaceuticals, we have validated the analytic techniques required to test the purity, potency, and stability of our medicine as required by the FDA and other regulators. We have advanced a generic ingredient (aviptadil) into a modern drug that meets GMP specifications, and that can be manufactured at commercial scale, cost, and shelf life," said Prof Jonathan Javitt, MD MPH Chairman and CEO NRx Pharmaceuticals. "While we continue to focus on proving clinical safety and efficacy in the treatment of COVID-19, we now have an investigational drug platform, reviewed by FDA, that enables us to investigate the use of ZYESAMI in both intravenous and inhaled form for a myriad of other lethal conditions that cause lung injury. Those conditions include Acute Respiratory Distress Syndrome (ARDS), Chronic Obstructive Pulmonary Disease (COPD), acute smoke inhalation, sarcoidosis, and checkpoint inhibitor pneumonitis, to name a few. The manufacturing information reviewed by the FDA will become part of our submission for New Drug Approval, while also providing support for a renewed EUA submission at such time as we have additional data to present."

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 (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. 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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Source: NRx Pharmaceuticals, Inc.