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NRx Pharmaceuticals Files New Breakthrough Therapy Designation Request for ZYESAMI® (aviptadil) in Subgroup of Patients with Critical COVID-19 with Respiratory Failure that were also treated with Remdesivir and continued to progress

- Breakthrough Therapy designation was requested based on data from post-hoc analysis of patients who in addition to Aviptadil or placebo were also treated with Remdesivir and whose respiratory failure due to Critical COVID-19 continued to progress.
- Submission includes cumulative safety data of approximately 750 patients treated with intravenous ZYESAMI® for Critical COVID-19

RADNOR, Pa., April 21, 2022 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals"), a clinical-stage, biopharmaceutical company, today announced that it has filed a new Breakthrough Therapy designation request with the U.S. Food and Drug Administration (FDA) focused on a subgroup of patients with Critical COVID-19 that in addition to aviptadil or placebo were also treated with remdesivir. The request includes safety data on approximately 750 patients treated with intravenous ZYESAMI® for Critical COVID-19.

NRx Files New BTD: ZYESAMI® shows highly significant four-fold increased odds of survival compared to placebo @ 60 days

NRx Pharmaceuticals submitted a Breakthrough Therapy designation request at the end of September 2021, which the FDA did not grant. In its reply, the FDA requested new clinical evidence comparing the safety and efficacy of aviptadil relative to other existing therapies for Critical COVID-19, such as remdesivir. Based on the FDA's input, NRx Pharmaceuticals performed a post-hoc analysis of its completed Phase IIb/III study focused on the approximately 70% of patients that continued to progress to COVID-19 respiratory failure that also received treatment with remdesivir. The post-hoc analysis showed that for these patients, who were already treated with remdesivir and continued to progress, ZYESAMI® showed a highly significant four-fold increased odds of survival compared to placebo at 60 days (P=.006). A Breakthrough Therapy designation request with this data had previously been submitted to the FDA, which NRx Pharmaceuticals withdrew to add its recently completed cumulative safety analysis of approximately 750 patients treated with intravenous ZYESAMI® for Critical COVID-19 to the submission. In February, NRx Pharmaceuticals submitted a new Emergency Use Authorization request also focused on this narrower patient population.

"In addition to the previously communicated efficacy data from the post-hoc analysis, this Breakthrough Therapy designation request also includes safety data of approximately 750 patients across all programs of intravenous ZYESAMI® in Critical COVID-19 as of early February 2022. Safety data is crucial and has been an area of focus of the FDA, given that in our Phase IIb/III study of Critical COVID-19 with 196 patients, only 131 received ZYESAMI® (aviptadil) and 65 received placebo. Our recently completed cumulative safety analysis identified no new adverse drug reactions and an overall safety profile of intravenous ZYESAMI® for Critical COVID-19 that is congruent with use in the ICU/Critical Care setting." said Robert Besthof, interim CEO of NRx Pharmaceuticals.

About NRx Pharmaceuticals

NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals" or the "Company") draws upon decades 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 in a Phase III trial for Critical COVID-19 patients which is sponsored and managed by the US National Institutes of Health. The FDA has additionally granted Breakthrough Therapy designation, a Special Protocol Agreement, and a Biomarker Letter of Support for NRX-101, an investigational medicine for the treatment of severe bipolar depression in patients with acute suicidal ideation and behavior (ASIB) after initial stabilization with ketamine or other effective therapy.

NRx Pharmaceuticals is led by executives and board members who have held senior roles at Lilly, Pfizer, GSK and the FDA. NRx Pharmaceuticals was co-founded by Prof Jonathan Javitt, MD, MPH, who has held leadership roles in various biotechnology startup companies and been appointed to advisory roles in four U.S. Presidential Administrations. The NRx Pharmaceuticals' board includes Dr. Sherry Glied, former U.S. Assistant Secretary for Health (ASPE), Chaim Hurvitz, former director of Teva and President of the Teva International Group, General H.R. McMaster, Ph.D. (US Army, Ret.), the 26th United States National Security Advisor, and Daniel E. Troy, J.D., former Chief Counsel of the FDA**.**

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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