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NRx Pharmaceuticals Provides Update on Breakthrough Therapy Designation (BTD) Request for ZYESAMI® (aviptadil)

RADNOR, Pa., June 10, 2022 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP, NRx Pharmaceuticals), ("NRXP" or the "Company"), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) denied the Breakthrough Therapy designation (BTD) request for ZYESAMI® (aviptadil) and emphasized its focus on the company's NRX-101 BTD compound for Bipolar Depression associated with Suicidality. The request for BTD was submitted based on the positive finding of a post-hoc subgroup 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.

"Although we are disappointed about FDA's decision, as recently announced, our strategic focus has already shifted to the advancement of our Breakthrough Therapy designation drug NRX-101. We expect topline data for our ongoing Phase II study of NRX-101 in patients with bipolar depression with sub-acute suicidal ideation (SSIB) by the end of the year. COVID-19, unfortunately, has also created a mental health crisis, including depression and suicides. Our commitment to helping patients with high unmet needs remains at the core of our work," said Robert Besthof, interim CEO of NRx Pharmaceuticals.

"Given ZYESAMI's mechanism and its well characterized safety profile, NRx Pharmaceuticals will further evaluate the options for its use in other high unmet pulmonary as well as other non-pulmonary indications."

About NRx Pharmaceuticals

NRx Pharmaceuticals, Inc. ("NRx Pharmaceuticals" or the "Company") draws upon decades of collective, scientific, and drug-development experience to address very high unmet needs of patients and bring improved health to patients. The U.S. Food and Drug Administration ("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 who have held leadership roles at Lilly, Pfizer, and Novartis as well as major investment banking institutions.

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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