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FDA Declines Emergency Use Authorization for ZYESAMI® (aviptadil) for subgroup of Patients with Critical COVID-19 at immediate risk of death from respiratory failure despite treatment with approved therapy, including remdesivir

Focus is now on NRX-101 for Bipolar Depression with Suicidality

RADNOR, Pa., July 1, 2022 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), ("NRx Pharmaceuticals"), a clinical-stage biopharmaceutical company, today announced that the US Food and Drug Administration (FDA) has declined to issue an Emergency Use Authorization (EUA) for ZYESAMI® (aviptadil) for a sub-group of patients that in addition to ZYESAMI®, also received Remdesivir and continued to progress. NRx Pharmaceuticals had submitted this last EUA application using data from a post-hoc subgroup analysis.

"As previously communicated, since the futility news of the ACTIV-3b / TESICO Study with ZYESAMI®, our team has already been highly focused on the development of NRX-101 for bipolar depression in patients with Acute and Sub-Acute Suicidality. Though disappointing, this decision by the FDA is not unexpected, given that they had already recently declined Breakthrough Therapy Designation for ZYESAMI®. We will evaluate the options for ZYESAMI® in COVID-19 respiratory failure and other lung disorders once we receive the full data set from the National Institutes of Health (NIH)," said Robert Besthof, interim CEO, NRx Pharmaceuticals.

About NRx Pharmaceuticals

NRx Pharmaceuticals, Inc. draws upon decades of collective, scientific, and drug-development experience applying innovative science to known molecules to address very high unmet needs and bring improved health to patients. The Company is developing NRX-101, its proprietary fixed dose combination as a treatment for Bipolar Depression in Patients with Acute Suicidal Ideation and Behavior (ASIB). The U.S. Food and Drug Administration ("FDA") has granted Breakthrough Therapy designation, a Special Protocol Agreement, and a Biomarker Letter of Support for NRX-101. 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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