



NRx Pharmaceuticals Announces Data Safety Monitoring Board (DSMB) Update on U.S. National Institutes of Health (NIH) Study of ZYESAMI® (aviptadil) in Critical COVID-19

- Based on a review of nearly 75% of the target enrollment of 640 patients, most of which have reached 90 days, the Independent DSMB overseeing the ACTIV-3b (TESICO) study determined that evaluation of aviptadil should cease due to futility
- ZYESAMI® (aviptadil) was the sole remaining investigational medicine in ACTIV-3b targeted at Critical COVID-19 patients
- ACTIV-3b Critical Care Study evaluated ZYESAMI and Veklury® (remdesivir), in Critical COVID-19 Patients, as monotherapy and in combination against placebo
- The DSMB stated there were no safety concerns for aviptadil

RADNOR, Pa., May 25, 2022 /[PRNewswire](#)/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals"), a clinical-stage biopharmaceutical company, today announced results of a review conducted by the Data Safety and Monitoring Board (DSMB) on May 25, 2022. The DSMB reviewed data of approximately 460 patients with Critical COVID-19 Respiratory Failure who were enrolled in the ACTIV-3b (TESICO) trial, most of which had reached the 90-day endpoint. The trial is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

The DSMB recommended stopping further randomization to aviptadil due to aviptadil not meeting the futility guidelines outlined by the pre-approved analytical plan. The primary endpoint (90 day 6-category ordinal score) was not supportive (OR 1.10; 0.79 – 1.54; p=0.56), and 90-day mortality secondary endpoint was also not supportive with 37% mortality in the aviptadil group vs 36% in the placebo group; HR 1.04 (0.77-1.41); p=0.79. There were no safety concerns, the known side effects of aviptadil (principally diarrhea and hypotension) were managed well with the protocols in place.

"We thank the NIH and the Trial Leadership for its extensive work in studying ZYESAMI® (aviptadil). We will continue to work closely with them to better understand the data over the coming months. This will also enable us to evaluate the options for ZYESAMI® in protecting the lung in other respiratory disorders, as well as its potential in other therapeutic areas," said Robert Besthof, Interim CEO of NRx Pharmaceuticals. "Critical COVID-19 remains a very high unmet need associated with significant mortality. "

"Our corporate focus remains to apply innovative science to known molecules in order to address very high unmet needs. We have a flexible infrastructure that allows us to focus our resources on our Breakthrough Therapy designation drug NRX-101. We are already actively enrolling patients in our Phase II study for bipolar depression in patients with Sub-acute Suicidal Ideation & Behavior (SSIB) and in the second half of the year we intend to start our Phase IIb/III registrational study for Severe Bipolar Depression in Patients with Acute Suicidal Ideation and Behavior (ASIB). "

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. 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, an investigational medicine for the treatment of severe bipolar depression in patients with acute suicidal ideation and behavior after initial stabilization with ketamine or other effective therapy. In addition, ZYESAMI® (aviptadil), for patients with COVID-19, has been granted Fast Track designation by the FDA and until recently, was enrolling in a Phase III trial for Critical COVID-19 patients which is sponsored and managed by the U.S. National Institutes of Health.

NRx Pharmaceuticals is led by executives who have held senior 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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