

# /CORRECTION---NeuroRx/

In the news release, NeuroRx Announces ZYESAMI<sup>™</sup> (aviptadil, RLF-100) Met the Primary Endpoint of Its Phase 2b/3 Clinical Trial and Also Demonstrated a Meaningful Benefit in Survival from Critical COVID-19, issued 29-Mar-2021 by NeuroRx over PR Newswire, we are advised by the company that more media contact information is needed to be included with the release. The complete, corrected release follows:

# NeuroRx Announces ZYESAMI™ (aviptadil, RLF-100) Met the Primary Endpoint of Its Phase 2b/3 Clinical Trial and Also Demonstrated a Meaningful Benefit in Survival from Critical COVID-19

RADNOR, Pa., March 29, 2021 /<u>PRNewswire</u>/ -- NeuroRx, Inc. today reports 60-day results of the Phase 2b/3 trial of intravenously-administered ZYESAMI<sup>TM</sup> (aviptadil acetate) for the treatment of respiratory failure in critically-ill patients with COVID-19, which is being developed in collaboration with Relief Therapeutics Holding AG (SIX:RLF, OTCQB:RLFTF). Across all patients and sites, ZYESAMI<sup>TM</sup> met the primary endpoint for successful recovery from respiratory failure at days 28 (P = .014) and 60 (P = .013) and also demonstrated a meaningful benefit in survival (P = < .001) after controlling for ventilation status and treatment site.

In addition to the robust overall significance across all 196 treated patients at all 10 clinical sites, the prespecified analysis of recovery from respiratory failure is clinically and statistically significant in the 127 patients treated by High Flow Nasal Cannula (HFNC) (P = .02), compared to those treated with mechanical or non-invasive ventilation at tertiary care hospitals. In this group, ZYESAMI<sup>™</sup>



patients had a 71% chance of successful recovery by day 28 vs. 48% in the placebo group (P = .017) and a 75% rate of successful recovery by day 60 vs. 55% in the placebo group (P = .036). Eighty-four percent (84%) of HFNC patients treated at tertiary medical centers with ZYESAMI<sup>M</sup> survived to day 60 compared with 60% of those treated with placebo (P = .007).

To the company's knowledge, ZYESAMI<sup>™</sup> is the first COVID-19 therapeutic to demonstrate advantages in both survival and recovery from critical COVID-19 in a randomized, double-blind multicenter trial. On the basis of these findings, NeuroRx plans to apply immediately to the United States Food and Drug Administration ("FDA") for Emergency Use Authorization (EUA) and to subsequently submit a New Drug Application (NDA).

Recovery from respiratory failure (without relapse) with discharge from acute care and survival through the observation period was the prespecified primary endpoint specified by FDA for the study, originally intended to be assessed at 28 days and then extended to 60 days based on recently-published FDA guidance. The above analysis includes all 196 participants who were randomized and treated in the placebo-controlled, double-blind clinical trial (<u>www.clinicaltrials.gov</u> NCT04311697) conducted at 10 US hospitals. Treatment with ZYESAMI™ or placebo was in addition to standard of care treatment that included steroids, convalescent plasma, antiviral therapy, anticoagulants, and various anti-cytokine drugs.

NeuroRx has announced the commencement of a clinical trial of inhaled ZYESAMI<sup>™</sup> for the treatment of patients with moderate and severe COVID-19 with the aim of preventing progression to respiratory failure. NeuroRx has also announced the inclusion of inhaled ZYESAMI<sup>™</sup> in the I-SPY clinical trial platform for patients with COVID-19

respiratory failure. The company has signed a clinical trial participation agreement with the National Institutes of Health.

The study's coordinating committee, including Professors Dushyantha Jayaweera, MD, FACP (University of Miami), Richard Lee, MD, (UC Irvine), and J. Georges Youssef, MD (Houston Methodist Hospital) commented, "*The 60-day observation framework implemented last month by FDA for critically ill patients with COVID-19 is more consistent with the clinical course of this lethal disease than the 28-day time frame originally adapted from other conditions that cause respiratory distress. The association of baseline oxygenation status (high flow nasal oxygen vs. ventilation) is not surprising in that patients who require mechanical or noninvasive ventilation in order to maintain blood oxygen are likely to have substantially more damage to the lining of their lungs compared to patients whose blood oxygen level can be maintained with high-flow oxygen delivered to the nose. The finding that patients fared substantially better in tertiary care centers as compared to regional hospitals may be influenced by the intensity of the public health crisis at the regional hospitals that participated in the study, all of which were operating at 200% or higher overcapacity in their intensive care units with implementation of temporary ICU beds and shortages of critical care staff."* 

Prof. Jonathan Javitt, MD, MPH, Chairman and CEO of NeuroRx, said, "ZYESAMI has now demonstrated itself in a phase 2/3 trial, conducted under FDA Fast Track Designation, not only to shorten hospitalization (as was previously reported) but also to save lives and increase the likelihood of patients returning safely home to their families. In exactly 12 months, a lifesaving drug has advanced from concept to clinical success in partnership with Relief Therapeutics in the midst of a public health emergency that has claimed the lives of millions. Today's findings confirm the often dramatic clinical success that has been seen in numerous patients treated in the US and abroad under emergency use protocols. We look forward to working with the National Institutes of Health, the Department of Defense, the FDA, and regulators around the world to bring this treatment to patients as quickly as possible."

An investor conference call will be held today, March 29th at 8:30am EDT. Participants can dial (+1) 866-373-3402 or join via webcast at <u>https://bit.ly/3sqPyDS</u>. Those wishing to ask questions should submit those questions to <u>ceo@nrxpharma.com</u>.

NeuroRx, Inc. has signed an agreement to merge with Big Rock Acquisition Corp. Details may be viewed at <a href="http://irdirect.net/filings/viewer/index/1719406/000119312521019278/">http://irdirect.net/filings/viewer/index/1719406/000119312521019278/</a>

# About VIP in COVID-19

Vasoactive Intestinal Polypeptide (VIP) was first discovered by the late Dr. Sami Said in 1970. Although first identified in the lung, it was purified from the intestinal tract. VIP is now known to be produced throughout the body and to be primarily concentrated in the lungs. VIP has been shown in more than 100 peer-reviewed studies to have potent anti-inflammatory/anti-cytokine activity in animal models of respiratory distress, acute lung injury, and inflammation. Most importantly, VIP binds specifically to the alveolar type II cell (ATII) in the air sac (alveolus) of the lung. VIP stimulates ATII cells to make the surfactant that must coat the lining of the lung in order for the lung to exchange oxygen with the blood. Loss of surfactant causes respiratory failure and alveolar collapse, which is a hallmark of COVID-19.

COVID-19-related respiratory failure is caused by selective infection of the ATII cell by the SARS-CoV-2 virus. The ATII cells are vulnerable because of their (ACE2) surface receptors, which serve as the route of entry for the virus. Coronavirus infection of the ATII cell shuts down surfactant production, triggers the formation of inflammatory cytokines, and causes cell death (cytopathy). VIP is shown to upregulate surfactant production, block Coronavirus replication in the ATII cell, block cytokine synthesis, and prevent viral-induced cell death (cytopathy). To our knowledge, other than ZYESAMI<sup>™</sup>, no currently proposed treatments for COVID-19 specifically target this mechanism of action.

#### About NeuroRx, Inc.

NeuroRx draws upon more than 100 years of collective drug development experience from senior executives of

AstraZeneca, Eli Lilly, Novartis, Pfizer, and PPD. In addition to its work on Aviptadil, NeuroRx has been awarded Breakthrough Therapy Designation and a Special Protocol Agreement to develop NRX-101 in suicidal bipolar depression and is currently in Phase 3 trials. Its executive team is led by Prof. Jonathan C. Javitt, MD, MPH, who has served as a health advisor to four Presidential administrations and worked on paradigm-changing drug development projects for Merck, Allergan, Pharmacia, Pfizer, Novartis, and Mannkind, together with Robert Besthof, MIM, who served as the Global Vice President (Commercial) for Pfizer's Neuroscience and Pain Division. NeuroRx recently announced a plan to complete a business combination with Big Rock Partners Acquisition Corp (NASDAQ:BRPA) ("BRPA"), and intends to apply for listing on the NASDAQ under the proposed symbol "NRXP".

## About Relief Therapeutics Holding AG

Relief focuses primarily on clinical-stage programs based on molecules of natural origin (peptides and proteins) with a history of clinical testing and use in human patients or a strong scientific rationale. Currently, Relief is concentrating its efforts on developing new treatments for respiratory disease indications. Its lead drug candidate RLF-100<sup>™</sup> (aviptadil) is being investigated in two placebo-controlled U.S. phase 2b/3 clinical trials in respiratory failure due to COVID-19. Relief also holds a patent issued in the United States and various other countries covering potential formulations of RLF-100<sup>™</sup>. Relief is listed on the SIX Swiss Exchange under the symbol RLF and quoted in the U.S. on OTCQB under the symbol RLFTF. www.relieftherapeutics.com.

### Cautionary Note Regarding Forward Looking Statements

Statements contained in this press release that are not historical facts may be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements generally relate to future events or NeuroRx's future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern NeuroRx's expectations, strategy, plans or intentions. Such forward-looking statements may relate to, among other things, the outcome of any discussions or applications for the future use of ZYESAMI, the approvals, timing, and ability to complete the proposed business combination with BRPA, and the combined company's ability to constitute guarantees of future performance and are subject to a variety of risks and uncertainties. NeuroRx does not undertake any obligation to update forward-looking statements as a result of new information, future events or developments or otherwise.

#### Additional Information and Where to Find It

This press release relates to a proposed business combination and related transactions (the "Transactions") between NeuroRx and BRPA. This press release does not constitute an offer to sell or exchange, or the solicitation of an offer to buy or exchange, any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, sale or exchange would be unlawful prior to registration or gualification under the securities laws of any such jurisdiction. BRPA has filed a registration statement on Form S-4 ("Registration Statement"), which includes a preliminary proxy statement for the solicitation of the approval of BRPA's stockholders, a preliminary prospectus for the offer and sale of BRPA's securities in the Transactions and a preliminary consent solicitation statement of NeuroRx, and other relevant documents with the SEC. The proxy statement/prospectus/consent solicitation statement will be mailed to stockholders of NeuroRx and BRPA as of a record date to be established for voting on the proposed business combination. INVESTORS AND SECURITY HOLDERS OF NEURORX AND BRPA ARE URGED TO READ THE REGISTRATION STATEMENT, PROXY STATEMENT/PROSPECTUS/CONSENT SOLICITATION STATEMENT AND OTHER RELEVANT DOCUMENTS THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTIONS. Investors and security holders will be able to obtain free copies of the registration statement, proxy statement, prospectus and other documents containing important information about NeuroRx and BRPA once such documents are filed with the SEC, through the website maintained by the SEC at http://www.sec.gov. In addition, copies of the documents filed with the SEC by BRPA can be obtained free of charge on BRPA's website at <u>www.bigrockpartners.com</u> or by directing a written request to BRPA at 2645 N. Federal Highway, Suite 230 Delray Beach, FL 33483.

#### Participants in the Solicitation

NeuroRx, BRPA and their respective directors and executive officers, under SEC rules, may be deemed to be participants in the solicitation of proxies of BRPA's stockholders in connection with the proposed Transactions. Investors and securityholders may obtain more detailed information regarding the names and interests in the proposed Transactions of NeuroRx's and BRPA's respective directors and officers in BRPA's filings with the SEC, including the proxy statement/consent solicitation statement/prospectus statement. You may obtain a free copy of these documents as described in the preceding paragraph.

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