NeuroRX and TFF Pharmaceuticals Announce Entering Into Feasibility Collaboration

March 9, 2021

Feasibility work underway to determine the compatibility of NeuroRx's ZYESAMI™ (aviptadil, synthetic VIP) as a dry powder formulation using TFF's Thin-Film Freezing technology

Dry powder inhalation technology has the potential to deliver ZYESAMI directly to the lungs

RADNOR, Pa. & AUSTIN, Texas--(BUSINESS WIRE)--Mar. 9, 2021-- NeuroRx, Inc. and TFF Pharmaceuticals, Inc. (NASDAQ: TFFP) are announcing that the companies have entered into a feasibility and material transfer agreement (Feasibility Agreement). Under the Feasibility Agreement, NeuroRx is delivering ZYESAMI™ (aviptadil, synthetic VIP) materials to TFF in order to perform feasibility formulation work and testing. The goal of this feasibility work is to formulate and identify an optimal, long-term stable formulation of ZYESAMI™ into a dry powder form, which has superior aerosol properties for delivery directly to the lungs.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210309005660/en/

ZYESAMI is a synthetic form of a naturally occurring peptide found in the lung called Vasoactive Intestinal Peptide (VIP), which is known to protect the Alveolar Type II cell that is targeted by the SARS-CoV-2 virus. The symptoms of COVID-19 are attributable to decreased surfactant production and increased cytokine production caused by Coronavirus infection of the Type II cell. This may also be a common pathway in sepsis-induced Acute Respiratory Distress Syndrome (ARDS) and Checkpoint Inhibitor induced pneumonitis associated with certain cancer drugs.

Loss of surfactant production in the lung may be the direct cause of the profound hypoxia or respiratory failure seen in COVID-19. The ability to deliver VIP directly to the lung via inhalation could have important therapeutic implications and potentially broaden the application of the drug to patients less severely affected with COVID-19.

"We are excited that ZYESAMI has demonstrated a highly significant reduction in time to hospital discharge for seriously ill COVID-19 patients treated with High Flow Nasal Oxygen, along with an increased likelihood of recovery and excellent safety," said Jonathan C. Javitt, M.D., M.P.H., CEO of NeuroRx. "Although our current production methods yield a drug that is sufficiently stable for emergency use, a long-term, shelf-stable formulation will be needed for ongoing use of ZYESAMI, once the pandemic subsides. The thin-film freezing technology holds great promise in potentially making this available to patients with other stages of COVID-19 with an inhaled form of ZYESAMI."

"The work being done by the NeuroRx team with ZYESAMI on behalf of critically ill patients with COVID-19 respiratory failure is both remarkable and gratifying," said Glenn Mattes, President & CEO of TFF Pharmaceuticals. "The potential opportunity to bring this important new therapeutic to patients earlier in the treatment cycle is exciting. We are very pleased to be collaborating with the NeuroRx Team with our thin-film freezing technology."

About VIP in COVID-19

Vasoactive Intestinal Polypeptide (VIP) was first discovered by the late Dr. Sami Said in 1970, for whom ZYESAMI™ is named. Although first identified in 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 500 peer-reviewed studies to have potent anti-inflammatory/anti-cytokine activity in animal models of respiratory distress, acute lung injury, and inflammation. Most importantly, 70% of the VIP in the body is bound to a rare cell in the lung, the alveolar type II cell (ATII), that is critical in the production of lung surfactant that is essential to transmission of oxygen from the air to the blood by the pulmonary epithelial cells that line the air sacs (alveoli) of the lung. Initial radiographic changes in COVID-19 are suggestive of collapse of these alveoli.

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. These specialized cells manufacture surfactant that coats the lung and is essential for oxygen exchange. Loss of surfactant causes collapse of the air sacs (alveolae) in the lung and results in respiratory failure.

VIP is shown to block Coronavirus replication in the ATII cell, block cytokine synthesis, block viral-induced cell death (cytopathy), and upregulate surfactant production. To our knowledge, other than ZYESAMI™, no currently proposed treatments for COVID-19 specifically target these vulnerable Type II cells. Recent laboratory findings suggest that VIP directly interferes with the spike protein complex of the SARS-CoV-2 virus.

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 ZYESAMI™, 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, M.D., M.P.H., 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". For more information, visit www.neurorxpharma.com.

About TFF Pharmaceuticals' Thin Film Freezing technology platform

TFF Pharmaceuticals' Thin Film Freezing (TFF) platform was designed to improve the solubility and absorption of poorly water-soluble drugs and is particularly suited to generate dry powder particles with properties targeted for inhalation delivery, especially to the deep lung, an area of extreme interest in respiratory medicine. The TFF process results in a "Brittle Matrix Particle," which possesses low bulk density, high surface area, and typically an amorphous morphology, allowing the particles to supersaturate when contacting the target site, such as lung tissue. Based upon laboratory experiments the aerodynamic properties of the particles are such that the portion of a drug deposited to the deep lung has the potential to reach as high as 75 percent.

About TFF Pharmaceuticals

TFF Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative drug products based on its patented Thin Film Freezing, or TFF, technology platform. Early testing confirms that the TFF platform can significantly improve the solubility and absorption of poorly water-soluble drugs, a class of drugs that comprises approximately one-third of the major pharmaceuticals worldwide, thereby improving their pharmacokinetics. TFF Pharmaceuticals has two lead drug candidates: Voriconazole Inhalation Powder and Tacrolimus Inhalation Powder. The Company plans to add to this pipeline by collaborating with large pharmaceutical partners. The TFF Platform is protected by 42 patents issued or pending in the US and internationally. To learn more about TFF Pharmaceuticals and its product candidates, visit the Company's website at https://tffpharma.com.

Cautionary Note Regarding Forward Looking Statements – TFF Pharmaceuticals:

This press release contains forward-looking statements regarding TFF Pharmaceuticals, Inc., including the benefits of the Company's TFF platform and a potential its dry powder version of NeuroRx's ZYESAMI. Those forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause actual results to differ materially. Among those factors are: (i) the risk that NeuroRx and the Company may not be able to produce a dry powder version NeuroRx's ZYESAMI, (ii) the risk that NeuroRx and the Company may not be able to successfully conclude clinical testing or obtain pre-market approval of a dry powder version of NeuroRx's ZYESAM, (iii) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, and (iv) those other risks disclosed in the section "Risk Factors" included in the Company's prospectus supplement filed with the SEC on December 8, 2020. TFF Pharmaceuticals cautions readers not to place undue reliance on any forward-looking statements. TFF Pharmaceuticals does not undertake, and specifically disclaims, any obligation to update or revise such statements to reflect new circumstances or unanticipated events as they occur, except as required by law.

Cautionary Note Regarding Forward Looking Statements – NeuroRx:

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 continue listing on Nasdaq after closing the proposed business combination. Such forward-looking statements do not 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 qualification 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 www.bigrockpartners.com 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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