UPDATE: NeuroRx Announces Dosing of First Patient with ZYESAMI™ in P2/3 Clinical Study for the Treatment of Moderate and Severe COVID-19 (AVICOVID-2)

March 19, 2021

RADNOR, Pa., March 19, 2021 (GLOBE NEWSWIRE) -- NeuroRx, Inc. announced the first patient in its P2/3 study of inhaled ZYESAMI™ in the treatment of moderate and severe COVID-19 (AVICOVID-2) was dosed at the University of California Irvine. The trial will be conducted at 10-15 clinical sites in the US.

To date, three clinical sites from the prior study have been initiated including University of California Irvine, Providence St. Jude Medical Center (Fullerton, CA), and University of Louisville. Due to limited resources and/or timing delays, some sites that had previously signaled participation and had been listed on *clinicaltrials.gov* are unable to participate or will join later. Those sites were recently removed from the listing. Various new sites are expected to be added in the coming weeks.

Jonathan C. Javitt, M.D., M.P.H., CEO of NeuroRx, stated, “Dosing of the first patient in this new study shortly after the last patient 60-day visit of our first study demonstrates our firm’s ability to deliver in this challenging environment. This new study is aimed at preventing patients from progressing to respiratory failure, and this medical concept is very appealing to clinical experts, as evidenced by numerous sites from our prior study participating or signaling interest to participate.”

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 proposed merger with Big Rock Partners Acquisition Corp. and a partnership agreement with Relief Therapeutics Holdings AG for the commercialization of RLF-100™ (aviptadil). For more information, please visit www.neurorxpharma.com.

CORPORATE CONTACTS

NeuroRx, Inc.
Jonathan C. Javitt, M.D., MPH
Chairman and Chief Executive Officer
ceo@neurorxpharma.com

INVESTOR RELATIONS

NeuroRx (United States)
Robert Besthof, MIM
Chief Commercial Officer
rbesthof@nrxpharma.com
484-254-6134

MEDIA CONTACT

NeuroRx (United States):
David Schull
Russo Partners, LLC
david.schull@russopartnersllc.com
858-717-2310

Source: NeuroRx, Inc.