# RELIEF THERAPEUTICS and NeuroRx, Inc. File FDA IND for Aviptadil to Treat COVID-19-induced Respiratory Distress

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**Aviptadil is a patented synthetic form of Vasoactive Intestinal Polypeptide that has previously shown promise in treating ARDS**

**- Coronavirus (COVID-19) death is primarily caused by Acute Respiratory Distress Syndrome (ARDS), in which severe inflammation causes the lungs to fill with fluid and even mechanical ventilation is unable to maintain life. The syndrome is caused by a Cytokine Storm unleashed by viral particles.**

**- VIP is known to have potent anti-cytokine effects in numerous animal models and in phase 1 and phase 2 human studies**

**- FDA has granted orphan drug status to Relief Therapeutics for the development of Aviptadil (VIP) in ARDS**

ZURICH, March 26, 2020 /PRNewswire/ -- RELIEF THERAPEUTICS Holding AG (SIX: RLF) "Relief", together with NeuroRx, a Delaware Corporation. have filed an Investigational New Drug (IND) Application with the US FDA for a phase 2 trial of RLF-100 (Aviptadil) in the treatment of Acute and Moderate Respiratory Distress in patients infected by the COVID-19 coronavirus. NeuroRx, Inc. is a privately held, drug development company that has previously demonstrated success in developing innovative drugs under FDA Fast Track, Breakthrough Therapy, and Special Protocol Agreement programs. Relief previously partnered with Biogen to develop Aviptadil for the treatment of pulmonary hypertension.

*"In a previous trial of VIP for ARDS caused by sepsis, 7 of 8 patients on mechanical ventilation showed substantial improvement and 6 ultimately left the hospital alive,"* said Prof. Jonathan Javitt, MD, MPH, the CEO of NeuroRx, Inc. and Vice Chairman[1] nominee of Relief. *"Patients on ventilators for COVID-19 have only a 50% chance of survival and if the early results can be replicated in ARDS caused by COVID-19, this treatment could have a major impact both on COVID-19 survival and on the availability of ventilators for those in desperate need. Should this trial demonstrate efficacy, Relief Therapeutics has sufficient immediately shippable drug substance to treat more than 100,000 Americans."*

Death in COVID-19-infected patients is caused by a "cytokine storm" in the lungs, in which the virus triggers inflammatory molecules called "cytokines," which cause the air sacs (alveolae) of the lungs to fill with water and become impermeable to oxygen, even in the setting of mechanical ventilation. VIP is a naturally synthesized peptide which is 40% concentrated in the lungs and which has been shown to have a potent anti-cytokine activity in numerous animal models of respiratory distress, acute lung injury, and inflammation. It has a 20-year history of safe use in human beings in multiple human trials for sarcoidosis, pulmonary fibrosis, and pulmonary hypertension, and is marketed in Europe as a local injection to treat erectile dysfunction. At an FDA public hearing in 2016[2], it was noted that more than 8,000 prescriptions for VIP were filled by a compounding pharmacy to treat a chronic inflammatory condition without any reported adverse events.

Relief Therapeutics holds FDA orphan drug designations for the use of VIP to treat ARDS, pulmonary hypertension, and sarcoidosis. Relief also holds a US patent[3] for Aviptadil and proprietary manufacturing processes for its synthesis.

"*Humanity is threatened by a deadly virus that has demonstrated a propensity to cause lethal ARDS. Conventional forms for respiratory support have so far failed to preserve life in half of those who develop ARDS in the setting of COVID-19 infection,*" commented Dr. Raghuram (Ram) Selvaraju, PhD, MBA, Chairman of Relief. "*We are cautiously optimistic that the early observations wherein RLF-100 7 of 8 patients with sepsis-related ARDS will carry over to today's crisis.*"

www.reliefthерapeutics.com

RELIEF THERAPEUTICS Holding AG is listed on the SIX Swiss Exchange under the symbol RLF.

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[1] Pending election at the upcoming General Assembly of Relief Shareholders
[2] FDA Pharmacy Compounding Advisory Committee, November 3, 2016
[3] US 8,178,489 Formulation for Aviptadil

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