VACCINE INFO

Aviptadil (RLF-100) COVID-19 Therapeutic

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Fact checked by **Robert Carlson, MD (https://www.precisionvaccinations.com/people/robert-carlson-md)**

Aviptadil COVID-19 Therapeutic Description

Aviptadil is a formulation of synthetic human Vasoactive Intestinal Peptide (VIP).

VIP is known to target the VPAC1 receptor of the ATII cell and to protect that cell against all manner of injuries, including smoke inhalation, exposure to stomach acid, and exposure to infectious agents. VIP prevents apoptosis, blocks cytokines, lowers TNFα levels, reverses CD4/CD8 ratio, and reduces cough and dyspnea in nonclinical and clinical studies.

Aviptadil COVID-19 Therapeutic has received orphan drug designation from the US Food and Drug Administration (FDA) in acute respiratory distress syndrome and chronic lung diseases

Aviptadil COVID-19 Therapeutic Indication

Aviptadil COVID-19 Therapeutic is being used to treat Novel Corona Virus (SARS-CoV-2) that is known to cause Respiratory Failure, which is the hallmark of Acute COVID-19, as defined by the new NIH/FDA classification.

Approximately 50% of those who develop Critical COVID-19 die, despite intensive care and mechanical ventilation.

Patients with Critical COVID-19 and respiratory failure, currently treated with high flow nasal oxygen, non-invasive ventilation or mechanical ventilation will be treated with RLF-100 (Aviptadil).

Aviptadil COVID-19 Therapeutic News

August 3, 2020 - According to the companies, the first report of rapid clinical recovery under emergency use of the drug was from Houston Methodist Hospital doctors.

August 2, 2020 - Critically ill COVID-19 patients recovered rapidly from respiratory failure after three days of treatment with RLF-100, a therapy granted fast-track designation in the United States, two drug companies said Sunday.

June 9, 2020 - Relief Therapeutics and NeuroRx have expanded the Phase II/III clinical trial of RLF-100 (Aviptadil) to include Covid-19 patients on ventilators, high flow oxygen, and noninvasive ventilation (CPAP).

Aviptadil COVID-19 Therapeutic Clinical Trials

Clinical Trial NCT04311697 : Intravenous Aviptadil for Critical COVID-19 With Respiratory Failure (COVID-AIV)

Clinical Trial NCT04453839 : RLF-100 (Aviptadil) Intermediate Population Expanded Access Protocol (SAMICARE)

- Patients with Critical COVID-19 and respiratory failure who are ineligible for enrollment in NCT04311697, who live more than 50 miles from an existing collaborating research center, or who are already hospitalized and cannot safely be transferred to a collaborating research facility may be considered for expanded access by the sponsor.

- Treating physicians must complete FDA Form 3396 and receive a letter of authorization from NeuroRx, along with local IRB authorization.

Clinical Trial NCT0436009 6 : Inhaled Aviptadil for the Treatment of Moderate and Severe COVID-19 (AVICOVID-2)

- SARS-CoV-2 virus infection is known to cause Lung Injury that begins as dyspnea and exercise intolerance, but may rapidly progress to Critical COVID-19 with Respiratory Failure and the need for noninvasive or mechanical ventilation. Mortality rates as high as 80% have been reported among those who require mechanical ventilation, despite best available intensive care.

- Patients with moderate and severe COVID-19 by FDA definition who have not developed respiratory failure be treated with nebulized RLF-100 (aviptadil, a synthetic version of Vasoactive Intestinal Polypeptide (VIP)) 100 µg 3x daily plus Standard of Care vs. placebo + Standard of Care using an FDA 501(k) cleared mesh nebulizer.

- The primary outcome will be progression to in severity of COVID-19 (i.e. moderate progressing to to severe or critical OR severe progressing to critical) over 28 days. Secondary outcomes will include blood oxygenation as measured by pulse oximetry, dyspnea, exercise tolerance, and levels of TNFα IL-6 and other cytokines.

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VACCINE NEWS

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First COVID Therapeutic To Block Replication of the SARS-CoV-2 in Human Lung Cells and Monocytes (/first-covid-therapeutic-block-replication-sars-cov-2-human-lung-cells-and-monocytes)

NeuroRx Aviptadil (RLF-100) is a patented formulation of Vasoactive Intestinal Polypeptide (/first-covid-therapeutic-block-replication-sars-cov-2-human-lung-cells-and-monocytes)

(/first-covid-therapeutic-block-replication-sars-cov-2-human-lung-cells-and-monocytes)

VACCINE DATA

Condition: COVID-19

Manufacturer: NeuroRx

Clinical Trial Phase I:
RLF-100 (Aviptadil) Intermediate Population Expanded Access Protocol (SAMICARE)

Clinical Trial Phase II: Intravenous Aviptadil for Critical COVID-19 With Respiratory Failure (COVID-AIV)

Clinical Trial Phase III:
Inhaled Aviptadil for the Treatment of Moderate and Severe COVID-19 (AVICOVID-2)

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