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Algeron Pharmaceuticals Announces Plans to Provide Interim Data from its Ifenprodil Phase 2b/3 COVID-19 Human Study

VANCOUVER, British Columbia, Nov. 09, 2020 (GLOBE NEWSWIRE) -- Algeron Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) (the "**Company**" or "**Algeron**") a clinical stage pharmaceutical development company, is pleased to announce that it plans to conduct an interim data review of its multi-national Ifenprodil Phase 2b/3 COVID-19 human study. The Company will look at the primary endpoint of the World Health Organization (WHO) ordinal score and also secondary endpoints including the number of days that patients were in the intensive care unit and the hospital, as well as the number of days patients were on mechanical ventilation, and oxygen.

The data, from 75 patients on day 15 of the study, will be presented in a descriptive statistics format and the Company is projecting the data readout will be in the first week of December 2020.

The Company decided to conduct an enhanced interim data readout because of the surge in serious cases as a result of the second wave of the COVID-19 pandemic seen globally, the number of recent adverse events and safety issues with vaccine and antibody trials, and the Company's belief that Ifenprodil has the potential to reduce the severity and duration of a COVID-19 infection.

"With the quickly increasing global threat from COVID-19, we believe we have an obligation to find out now how our COVID-19 trial is trending," said Christopher J. Moreau, CEO of Algeron Pharmaceuticals. "If Ifenprodil has been performing well in the study, this early look at the data may allow us to accelerate our COVID-19 program accordingly."

The Company advises that it is not making any express or implied claims that Ifenprodil has the ability to eliminate, cure or contain COVID-19 (or the SARS-2 Coronavirus) at this time.

Phase 2b/3 Study Protocol Summary

The Company's multinational Phase 2b/3 human trial for COVID-19 is entitled, "A Randomized Open Label Phase 2b/3 Study of the Safety and Efficacy of NP-120 (Ifenprodil) for the Treatment of Hospitalized Patients with Confirmed COVID-19 Disease."

The trial has begun as a Phase 2b study of an aggregate of 150 patients. With positive data, the clinical trial will move directly into a Phase 3 trial. The data from the Phase 2b study will determine the number of patients needed to reach statistical significance in the Phase 3 trial.

Patients are being randomized in a one-to-one manner and will either be treated using an existing standard of care, or standard of care plus Ifenprodil 60 mg (taken as one 20 mg tablet three-times daily) for one arm or standard of care plus Ifenprodil 120 mg (taken as two 20 mg tablets three-times daily) for two weeks.

Over the testing period, doctors will observe whether there is an improvement in a number of secondary endpoints, including mortality, blood oxygen levels, time spent in intensive care and time to mechanical ventilation.

About NP-120 (Ifenprodil)

NP-120 (Ifenprodil) is an N-methyl-D-aspartate (NMDA) receptor antagonist specifically targeting the NMDA-type subunit 2B (GluN2B). Ifenprodil prevents glutamate signalling. The NMDA receptor is found on many tissues including lung cells, T-cells, and neutrophils.

The Company believes Ifenprodil can reduce the infiltration of neutrophils and T-cells into the lungs where they can release glutamate and cytokines respectively. The latter can result in the highly problematic cytokine storm that contributes to the loss of lung function and ultimately death as has been reported in COVID-19 infected patients.

About Algernon Pharmaceuticals Inc.

Algernon is a drug re-purposing company that investigates safe, already approved drugs for new disease applications, moving them efficiently and safely into new human trials, developing new formulations and seeking new regulatory approvals in global markets. Algernon specifically investigates compounds that have never been approved in the U.S. or Europe to avoid off label prescription writing.

Algernon has filed new intellectual property rights globally for NP-120 (Ifenprodil) for the treatment of respiratory diseases and is working to develop proprietary injectable and slow release formulations.

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Source: Algernon Pharmaceuticals