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Algernon Pharmaceuticals Announces 154 Patients Enrolled in its Multinational Phase 2b/3 Human Study of Ifenprodil for COVID-19

VANCOUVER, British Columbia, Nov. 23, 2020 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) (the “**Company**” or “**Algernon**”) a clinical stage pharmaceutical development company, is pleased to announce that it has now enrolled 154 patients in its multinational Phase 2b/3 human study of NP-120 (Ifenprodil) for the treatment of COVID-19.

Due to attrition, which is a common occurrence in clinical trials, the Company has decided to increase the total number of patients in the study to 168 in order to compensate. As a result, the Company will be adding an additional 14 patients before it announces that enrollment in the study has closed.

“We are almost there in terms of completing patient enrollment,” said Christopher J. Moreau CEO of Algernon Pharmaceuticals. “Sometimes when a study has a group that does not receive the treatment drug, you see a higher percentage of patients dropping out, than is typically seen. By adding approximately 12% to the original target total of 150 patients, we should be able to ensure we achieve the proper study size to power our data calculations.”

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 preliminary 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 (Glu2NB). 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 a proprietary injectable and slow release formulation.

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Source: Algeron Pharmaceuticals