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Algernon Pharmaceuticals Announces Enrollment of Final Patient in its Multinational Phase 2b/3 Human Study of Ifenprodil for COVID-19

VANCOUVER, British Columbia, Nov. 30, 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 the final patient has been enrolled in its multinational Phase 2b/3 human study of NP-120 (Ifenprodil) for the treatment of COVID-19. The aggregate total number of patients enrolled from all countries participating in the study is 168.

The Company recently announced that it would be providing interim data from 75 patients from day 15 of their participation in the study, in the first week of December. Since the treatment period after enrollment is two weeks, with a two-week follow-up thereafter, the interim data readout date has now been moved to the third week of December to ensure that the patients who recently enrolled, can complete their treatment regimen before data is presented.

The Company will update the market shortly on the date when the final data readout will be available.

“I want to thank to the entire AGN team, including all of our clinical trial investigators and their staff, for helping us reach the goal of 100% patient enrollment,” said Christopher J. Moreau CEO of Algernon Pharmaceuticals. “Our next big step is to see how the preliminary data is trending and we remain hopeful it will show that Ifenprodil is reducing both the severity and duration of a COVID-19 infection. Even with the recent success of certain vaccines in clinical trials, medical doctors need to have effective therapeutic treatment options as well.”

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: Algernon Pharmaceuticals