Algernon Announces Enrollment of First Patient in 2b/3 Human Study of Ifenprodil for Treatment of COVID-19

VANCOUVER, British Columbia, Aug. 05, 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 enrolled its first patient in its multinational Phase 2b/3 human study of NP-120 (Ifenprodil) for the treatment of COVID-19**.** The countries participating in the study include the U.S., Australia, Romania and the Philippines.

"On March 6th, 2020 the company announced it had decided to explore Ifenprodil as a possible treatment for COVID-19 and 5 months later we have now begun a Phase 2b/3 human trial," said Christopher J. Moreau CEO of Algernon Pharmaceuticals. "We look forward to a speedy enrollment of the balance of the patients and we remain hopeful in Ifenprodil's potential as a therapeutic that will reduce both the severity and duration of a COVID-19 infection."

Background

The Company announced on March 06, 2020 that it was going to explore Ifenprodil as a possible treatment for COVID-19 when it discovered an independent research study that showed the drug was active in an animal model for H5N1, the world's most lethal avian flu, with an approximately 60% mortality rate in humans. In the study, Ifenprodil reduced mortality by 40% and reduced acute lung injury and inflammation in the lung tissue.

On July 21, 2020 the Company highlighted a study undertaken by UT Dallas that identified a dramatic upregulation of NMDA receptors in immune cells in the lungs of COVID-19 patients. The study went on to identify possible drug candidates, including Ifenprodil, that could interfere with the receptor's glutamate signalling pathway and as a result possibly reduce the severity and duration of a COVID infection. Ifenprodil is an N-methyl-D-aspartate (NMDA) receptor antagonist specifically targeting the NMDA-type subunit 2B (Glu2NB) preventing glutamate signalling.

Coupled with the Company's own animal data showing Ifenprodil's reduction of lung fibrosis in two separate studies, and its efficacy in an animal model for acute cough, the Company is investigating Ifenprodil to determine if it can reduce the severity and duration of a COVID infection.

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 will begin 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 will determine the number of expected patients needed to reach statistical significance in the Phase 3 trial.

Patients will be 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.

Phase 2b Study Completion and Data Readout

Now that the study has begun, the Company will make an assessment of the enrollment rate and will provide an update to the market in due course on a projected completion date as well as when the read out of the data can be expected.

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 NP-120 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.

The Compay is not making any express or implied claims that NP-120 (Ifenprodil) is an effective treatment for COVID-19.

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