ALGERNON RECEIVES ETHICS APPROVAL FOR U.S. SITES FOR 2B/3 HUMAN STUDY OF IFENPRODIL FOR COVID-19

VANCOUVER, British Columbia, June 25, 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 received ethics approval from a central institutional review board for U.S. study sites for its multinational Phase 2b/3 human study of NP-120 (Ifenprodil) for COVID-19**.** Ifenprodil is an NMDA receptor antagonist specifically targeting the NMDA-type subunit 2B.

The Company is also pleased to provide the following update to the market on its general progress regarding the study as well as other business activities.

Phase 2b/3 Study for COVID-19

Overview

The Company is advancing on its multinational Phase 2b/3 human trial for COVID-19 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 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.

Coupled with the Company's own animal data showing Ifenprodil's reduction of lung fibrosis in two separate studies, 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

Based on additional feedback from the U.S. FDA, the Company is planning to increase the size of the Phase 2b part of the study from 100 to 150 patients by adding a second treatment arm where patients receive a higher dose of Ifenprodil.

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 study. The Phase 2b data will determine the number of expected patients needed to reach statistical significance in the Phase 3 trial.

Patients will be randomized in a 1:1:1 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), or standard of care plus Ifenprodil 120 mg (taken as two 20 mg tablets three-times daily).

The primary endpoint will be the change in a patient's clinical score using the World Health Organization's ordinal scale. In addition, 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.

Participating Countries

The Company has received regulatory clearance from the U.S. FDA and Health Canada. In an effort to ensure the timely enrolment of the 150 COVID confirmed hospitalized patients in as short a time period as possible, the Company requested Novotech, its CRO partner, to identify two additional countries to add to the multinational study.

As a result, Novotech has been conducting a feasibility study in the Philippines and Romania, where they have established relationships with researchers and institutions, and where there are still a significant number of confirmed COVID cases.

There will be no pre-set number of patients assigned per site, and the goal is to reach the enrollment number of 150 patients as soon as possible across all sites and all countries.

Research Institutions

The Company is working with five study sites in the U.S. and has completed all site selection visits and is working to finalize all contract negotiations. The Company has also received approval from a central institutional review board that applies to all sites. The states where the institutions are located include Florida, Illinois, Missouri and Ohio.

The Company has also signed agreements with two research sites in Australia and one in Romania. Ethics approval for the study has been submitted in Australia and will be submitted for Romania and the Philippines shortly.

The Company is also in discussions with a short list of sites in Canada, however, there has been a significant decline in confirmed hospitalized cases in the country.

Study Start Date

Enrollment of the 1st patient for the Phase 2b/3 study is expected before the end of July 2020. It is difficult to assess at this time what the enrollment rate for the study will be across all countries and all sites selected.

However, based on the rising number of reported COVID infections in certain countries, the Company is presently not concerned about achieving the enrollment of the 150 patients for its study in a reasonable time period. After the study begins, the Company will make an assessment

of the enrollment rate and will provide an update to the market on a projected competition date as well as when the data will be expected.

Investigator-led COVID Study in South Korea

One research site was initiated at the end of May 2020 and two sites were initiated in early June for the investigator-led COVID Phase 2 trial in South Korea. Dr. Dong Sik Jung, Professor, in the Division of Infectious Disease of Dong-A University Hospital, has now begun the process of screening patients. Up until recently, there has been a dramatic reduction in a lack of sufficiently ill patients with pneumonia, which is a requirement for patients to be enrolled in this study. Over the last number of months, the South Korean government has worked diligently to contain and minimize COVID-19 and the result has been a dramatic reduction in severe cases.

South Korea was chosen as an initial study location because it is one of two countries where Ifenprodil is currently approved for the treatment of vertigo and dizziness. The Company had high expectations that an off-label trial of an Ifenprodil COVID study would achieve both regulatory and ethics approval, which was received. In March 2020, when the Company began to explore Ifenprodil as a possible treatment for COVID, it was not known at the time how the U.S. FDA or Health Canada would respond to a clinical trial application for Ifenprodil, since the drug had not been previously approved in either country.

Ifenprodil Manufacturing

The Company retained Cascade Chemistry, a US based CRO specializing in chemical synthesis, to scale-up cGMP manufacturing of Ifenprodil.

The Company requires the active pharmaceutical ingredient (API) of Ifenprodil in order to develop new formulations of the drug including an injectable and a slow release tablet. Cascade is nearing completion of its first engineering run of API with the cGMP synthesis to begin shortly.

The Company is also working with the U.S. FDA on its plans to have finished product of Ifenprodil manufactured and available in as short a time frame period as possible, should the Phase 2b/3 trial achieve positive results.

Cash Position

The Company currently has an approximate cash balance of CDN $7.5M. The Company believes the funds on hand will be sufficient to cover the costs of the company's Phase 2 IPF and chronic cough study, the cost of supporting the investigator-led Phase 2 COVID study in South Korea and the multinational Phase 2b/3 COVID study, to their full conclusion, including all general operating expenses.

"We continue to get closer to dosing our first patient in our Phase 2b/3 human trial investigating Ifenprodil for COVID," said Christopher J. Moreau, CEO of Algernon Pharmaceuticals Inc. "There is a tremendous amount of work involved and many moving parts to getting a multinational

clinical trial underway once regulatory approvals are received and we will continue to update the market as we progress."

The Company cautions that while it will begin its Phase 2b/3 clinical trial shortly, it is not making any express or implied claims that Ifenprodil is an effective human treatment for acute lung injury (ALI), the COVID-19 virus, or any other medical condition at this time.

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.

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