ALGERNON RECEIVES U.S. FDA CLEARANCE FOR MULTINATIONAL PHASE 2B/3 HUMAN STUDY TO EVALUATE IFENPRODIL AS A POTENTIAL THERAPEUTIC FOR COVID-19

VANCOUVER, British Columbia, June 04, 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, on June 3rd, 2020, clearance from the U.S. FDA for its recently submitted Investigational New Drug (IND) application for its planned multinational Phase 2b/3 study of its re-purposed drug NP-120 (Ifenprodil) as a potential therapeutic treatment for patients with COVID-19. Ifenprodil is an NMDA receptor antagonist.

The clinical study for Ifenprodil is entitled, "A Randomized Open Label Phase 2b/3 Study of the Safety and Efficacy of NP-120 (Ifenprodil) for the Treatment of Confirmed COVID-19 Infected Hospitalized Patients." As part of the multinational Phase 2b/3 COVID-19 clinical study, Algernon has already received clearance in Canada and has also filed for ethics approval in Australia.

"We very much appreciated the timely responses that we have received from the U.S. FDA since we first began working with the agency on our COVID-19 clinical trial program," said Christopher J. Moreau, CEO of Algernon Pharmaceuticals Inc. "We have already begun the background work to start the Phase 2 trial in the U.S. and other countries as soon as possible and we will update the market shortly on our planned timelines."

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

Phase 2b/3 Study Summary:

Once local ethics approvals have been received, the trial will begin as a Phase 2b study of an aggregate of 100 patients and with positive preliminary data, the clinical trial will move directly from a Phase 2b 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 a 20mg dose of Ifenprodil taken three times a day 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 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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