

July 16, 2020



Algernon Announces First U.S. Clinical Trial Site in Florida for Phase 2b/3 Human Study of Ifenprodil for COVID-19

VANCOUVER, British Columbia, July 16, 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 completed its clinical trial agreement with Westchester Research Center at Westchester General Hospital in Miami, Florida, for its multinational Phase 2b/3 human study of NP-120 (Ifenprodil) for COVID-19. The principal investigator is Dr. Aimee Gonzalez, MD. Ifenprodil is an NMDA receptor antagonist specifically targeting the NMDA-type subunit 2B.

The Company is planning to conduct a site initiation visit at Westchester General Hospital during the week of July 20, 2020 and enrolment of patients in the study can begin shortly thereafter.

The Company is in final contractual negotiations with 4 additional U.S. clinical sites. The Company has already received ethics approval from a central institutional review board for all of the U.S. study sites. The Company is also in the final stages of completing contractual negotiations and receiving ethics approval in Australia, Romania and the Philippines.

“Of the 5 U.S. research institutions we have been working with, two are located in Florida where they have recently had a significant number of confirmed COVID-19 cases,” said Christopher J. Moreau CEO of Algernon Pharmaceuticals. “We look forward to working with Dr. Gonzalez and appreciate her work in helping to get the trial started at Westchester General as soon as possible.”

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.

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

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.

Trial 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. 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 completion date as well as when the data will 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.

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Source: Algernon Pharmaceuticals