

May 15, 2020



Algernon Submits for Ethics Approval in Australia for Multinational Phase 2b/3 Human Study of Ifenprodil for COVID-19

VANCOUVER, British Columbia, May 15, 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 submitted for ethics approval in Australia for its planned multinational Phase 2b/3 study of its re-purposed drug NP-120 (Ifenprodil) for COVID-19. The ethics submission was made at Princess Alexandra Hospital located in Brisbane, Queensland.

In addition to Australia, the Company is also planning to conduct the multinational phase 2b/3 clinical study in Canada and the U.S. Algernon has already received clearance for the clinical study in Canada and is preparing to file an investigational new drug (IND) application with the U.S. FDA.

“Thanks to the hard work of our CRO partner Novotech, this ethics submission is yet another important step in the Company’s COVID-19 clinical development program,” said Christopher J. Moreau, CEO of Algernon Pharmaceuticals Inc. “The Algernon team is working hard to finalize the U.S. FDA IND application and will be updating the market on its progress shortly.”

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 NP-120 (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 all ethics approvals have been received, the trial will begin as a Phase 2b study 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 and T-cells, 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: Algergon Pharmaceuticals