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Algernon Announces Data and Safety Monitoring Board Recommends the Continuation of its Multinational 2b/3 Human Study of Ifenprodil for Treatment of COVID-19

VANCOUVER, British Columbia, Sept. 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 the external Data and Safety Monitoring Board (DSMB) has unanimously approved the continuation of its multinational Phase 2b/3 human study of NP-120 (Ifenprodil) for the treatment of COVID-19. The DSMB is a committee of clinical research experts, such as physicians and statisticians, and patient advocates who monitor the progress of a clinical trial and review safety and effectiveness data while the trial is ongoing.

This recommendation from the DSMB is encouraging because it confirms that there are no significant safety concerns in the study groups being treated with Ifenprodil.

“We are very pleased with the unanimous decision of the DSMB to carry on with the study,” said Christopher J. Moreau CEO of Algernon Pharmaceuticals. “It confirms what we had previously identified regarding Ifenprodil’s long standing safety history.”

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 is currently underway 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 from the Phase 2b study will determine the number of patients needed to reach statistical significance in the Phase 3 trial.

Patients are being randomized in a one-to-one manner and are either being 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

The Company will provide an update to the market on a projected completion date of the study as well as when the read out of the data can be expected when enrollment in the study reaches the 50% target level.

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 Ifenprodil 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.

CONTACT INFORMATION

Christopher J. Moreau
CEO
Algernon Pharmaceuticals Inc.
604.398.4175 ext 701
info@algernonpharmaceuticals.com
investors@algernonpharmaceuticals.com
www.algernonpharmaceuticals.com

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Source: Algernon Pharmaceuticals