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Algernon Pharmaceuticals Announces Positive Trending Interim Data for its Phase 2b/3 Ifenprodil COVID Study

VANCOUVER, British Columbia, Dec. 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 report, in a descriptive format, positive trending interim data for the Phase 2b part of the Company's Phase 2b/3 clinical study of Ifenprodil for COVID-19.

For the endpoint of ventilation by day 15, there was a trend towards fewer patients requiring mechanical ventilation in the high dose Ifenprodil treatment arm, as compared to patients who were in the untreated arm of the study. Mechanical ventilation is associated with poor prognosis in COVID-19 patients, including increased risk of mortality and procedural complications.(1) In addition, extended duration of mechanical ventilation places an enormous burden on ICUs and entire hospital systems.

Although all patients had similar mean WHO and NEWS scores at day 15, there was a trend in the high dose group of Ifenprodil patients to reduce the NEWS score more quickly than control after treatment was initiated. This may suggest that patients are recovering more quickly. If a patient is recovering earlier, it could result in a reduction in the number of days in hospital. A number of other COVID-19 therapeutics have received emergency use authorization from the U.S. FDA based solely on reducing the number of days in hospital. This endpoint was not included in this interim analysis, but will be reported in the final data set.

The Company also notes that a review of adverse events indicated that Ifenprodil was generally well tolerated and that no new serious safety concerns have been identified. The majority of adverse events were mild or moderate in severity. A continuous review of safety data is ongoing.

While the Company originally advised that the interim data set would be based on 75 patients, this was increased to up to 123 patients for some of the endpoints owing to the availability of the data.

In addition to including full statistics, there will be additional key endpoints reported in the final data set of the Phase 2b part of the study that are not in the interim data set, such as time to discharge from the hospital, and time on mechanical ventilation.

The objective of the Phase 2b part of the trial is to inform the Company what the most appropriate endpoint target(s) should be for the Phase 3 part of the study, as well as how many patients would be required to achieve statistical significance.

Based on the date the last patient was enrolled in the study, the Company is projecting the final Phase 2b data set will be available in Q1 2021.

“While we are very pleased that the interim data has provided us with some positive trending information, we still need to evaluate the full definitive results and statistics to be presented with the final data set,” said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. “We will be especially interested to see the numbers on the overall time spent on ventilation and rate to ventilation to be reported in the final data set.”

The Company advises that it is not making any express or implied claims that Ifenprodil has the ability to eliminate, cure or contain COVID-19 (or the SARS-2 Coronavirus) at this time.

(1) Botta et al. Ventilation management and clinical outcomes in invasively ventilated patients with COVID-19 (PRoVENT-COVID): a national, multicentre, observational cohort study. Lancet Respir Med 2020 https://doi.org/10.1016/S2213-2600(20)30459-8.

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 proprietary injectable and slow release formulations.

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