

Algernon Pharmaceuticals Provides Additional Information on Phase 2b/3 Ifenprodil COVID-19 Study Interim Data

VANCOUVER, British Columbia, Dec. 17, 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 provide additional information on its interim data report for the Phase 2b part of the Company’s Phase 2b/3 clinical study of Ifenprodil for COVID-19.

Phase 2b/3 Trial Endpoints

The Algernon Phase 2b/3 COVID-19 clinical trial protocol design was based on WHO guidelines (master protocol version 2.0, February 24, 2020). This design allows for a secondary endpoint to be used as the primary endpoint going forward in the Phase 3 part of the trial.

The objective of the Phase 2b part of the trial is to investigate multiple endpoints and identify those that show the best efficacy. This was anticipated and was accounted for by the WHO clinical trial guidelines.

Additionally, after the Company finalized its investigational new drug application (IND), the U.S. FDA (FDA), updated its guidance on COVID-19 clinical trials stating a preference for a respiratory failure-based endpoint as an alternative to the WHO score as the primary efficacy endpoint for the Phase 3 portion of the trial.

Finally, due to the complexity of clinical trials, one endpoint can show efficacy while other endpoints do not. For example, in Algernon’s interim data, 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, even though all patients had similar mean WHO and NEWS scores.

FDA Accepted COVID-19 Trial Endpoints

Algernon has a number of FDA accepted COVID-19 efficacy endpoints⁽¹⁾ in its trial Phase 2b/3 trial design including:

- Respiratory failure (including need for mechanical ventilation)
- Need for Intensive care
- Need for hospitalization
- Objective measure of sustained improvement (e.g., oxygenation)
- Ordinal measures of clinical improvement (e.g., WHO, NEWS scores)
- Mortality

FDA Emergency Use Authorization (EUA)

Algernon has always planned to consult with the FDA on a possible path to EUA after the Phase 2b final data set is completed.

“The Company believes that the interim data represents a very positive step in the investigation of Ifenprodil as a potential therapeutic treatment for COVID-19,” said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. “We were very pleased to see positive trending data with a ventilation related endpoint that is favoured by the FDA for COVID-19 trials. Further, Algernon has only provided interim data on three endpoints from day 15 of its 30-day Phase 2b/3 Ifenprodil COVID-19 study, with the majority of the data still to be reported.”

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) <https://www.fda.gov/media/137926/download>

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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Source: Algernon Pharmaceuticals