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.

CONTACT INFORMATION

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

Neither the Canadian Securities Exchange nor its Market Regulator (as that term is defined in the policies of the Canadian Securities Exchange) accepts responsibility for the adequacy or accuracy of this release. The Canadian Securities Exchange has not in any way passed upon the merits of the proposed transaction and has neither approved nor disapproved the contents of this press release.

CAUTIONARY DISCLAIMER STATEMENT: No Securities Exchange has reviewed nor accepts responsibility for the adequacy or accuracy of the content of this news release. This news release contains forward-looking statements relating to product development, licensing, commercialization and regulatory compliance issues and other statements that are not historical facts. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects" and similar expressions. All statements other than statements of historical fact, included in this release are forward-looking statements that involve risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company's expectations include the failure to satisfy the conditions of the relevant securities exchange(s) and other risks detailed from time to time in the filings made by the Company with securities regulations. The reader is cautioned that assumptions used in the preparation of any forward-looking information may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking information. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. The forward-looking statements contained in this news release are made as of the date of this news release and the Company will update or revise publicly any of the included forward-looking statements as expressly required by applicable law.