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Algernon Pharmaceuticals to File End-of-Phase 2 Meeting Request with U.S. FDA for Possible Ifenprodil Phase 3 COVID-19 Trial

VANCOUVER, British Columbia, April 08, 2021 (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 plans to formalize discussions with the U.S. Food and Drug Administration ("FDA") by filing an End-of-Phase 2 meeting request (EOP2) based on the completion of the Phase 2b part of its Phase 2b/3 COVID-19 trial (the "Study") of NP-120 (Ifenprodil).

Algernon has now completed its initial review of the full data set from the Study and will be seeking guidance from the FDA on moving forward with a potential Phase 3 study.

The purpose of an EOP2 meeting is to facilitate interaction between the FDA and sponsors who seek guidance related to clinical trial design, to determine the safety of proceeding to Phase 3, to evaluate the Phase 3 plan, including protocols and endpoints for adequacy, and to identify information necessary to support a marketing application.

As part of the EOP2 meeting request, the Company is preparing a briefing package that includes a summary of Study data and a protocol synopsis for a potential Phase 3 trial. The EOP2 meeting is an essential part of the process to help guide the Company and determine the next steps forward.

The EOP2 meeting will focus on the data from three key endpoints from the Study including all-cause mortality, oxygenation (SpO2) and time in ICU, from the 20mg Ifenprodil treatment arm.

The Company has been reviewing the data from the 40mg Ifenprodil treatment arm of the Study. While the full data set review confirmed no significant changes were observed compared to the untreated arm of the Study, the data showed a negative dose effect trend with some clinical outcomes.

As a complex receptor, NMDA's relationship with drugs that stimulate or inhibit it is not completely understood. In some cases of being inhibited or antagonized, the receptor, instead of shutting down, appears to protest over-inhibition, possibly leading to adverse responses in patients. This has been identified in studies of Memantine and Ketamine, also NMDA receptor antagonists.

This may represent a class effect observed at doses higher than those at which a more customary dose-response relationship is shown, and as such, may inform observations on the 40mg dose data. There was very little historical data to guide dosing for this Study of

Ifenprodil in COVID-19 patients, and the Company chose to include a high dose 40mg treatment arm in the Study, in view of Ifenprodil's considerable safety record.

"When we consider the totality of the Study's data set, we are very confident that the next appropriate step is a formal EOP2 meeting with the FDA in order to discuss the results and explore the potential of a Phase 3 trial," said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. "We look forward to feedback from the FDA so that we can determine our next steps."

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.

About Algernon Pharmaceuticals Inc.

Algernon is a drug re-purposing company that investigates well-tolerated, already approved drugs, including naturally occurring compounds 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.

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Source: Algernon Pharmaceuticals