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Algernon Pharmaceuticals Announces Topline Data From its Phase 2b/3 COVID-19 Trial of Ifenprodil

VANCOUVER, British Columbia, March 31, 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 topline data from the Phase 2b part of its Phase 2b/3 COVID-19 trial of NP-120 (Ifenprodil).

The purpose of the Phase 2b part of the study was to identify one or more approvable U.S. FDA endpoints that showed a strong enough signal to consider moving forward into a Phase 3 study.

Key topline findings include:

All Cause Mortality:

At Day 15 of the study (the last day of treatment) there was 0% mortality in the 20 mg dose Ifenprodil treatment arm compared to a 3.3% mortality rate in the untreated control arm, p=0.18. For a Phase 3 trial to be sufficiently powered to confirm this endpoint, it is projected that 1,900 patients would need to be enrolled to reach a statistically significant result.

Oxygenation (SpO_2):

Of patients with a low blood oxygen level (SpO_2 <94%), 100% of patients in the 20 mg dose treatment arm returned to normal levels of oxygen at day 4 compared to day 9 for patients in the untreated arm (adjusted hazard ratio 1.91, 95% CI 0.97-3.77, p=0.061). Power calculations project that 450 patients would be required to confirm a statistically significant result with this endpoint in a Phase 3 trial.

Time in ICU:

Topline results for this endpoint indicate that there was also a strong trend to less time spent in the ICU in the overall study by patients in the 20 mg dose arm, as compared to patients in the untreated arm (adjusted hazard ratio 10.45, CI 1.23-88.61, p=0.0315). However, the Company cautions that additional, confounding variables were detected, and these numbers need to be confirmed with additional analysis, as well as power calculations conducted to project the required size for a Phase 3 study.

WHO Score and Other Endpoints:

The WHO score, the primary default endpoint for the study, showed a similar mean in all patients in all study arms. No significant changes were seen in other secondary endpoints, namely the time to hospital discharge, rates and duration of mechanical ventilation, or the NEWS score.

The Company investigated a 20 mg and 40 mg dose of Ifenprodil. Based on the initial data review, no significant changes were observed in the 40 mg dose group.

The Company intends to discuss the results of the trial with the U.S. FDA once the final data set has been fully reviewed and intends to present the complete data set in a peer-reviewed journal at a later time.

"The Company has done a tremendous amount of work in a very short period of time to get to this stage to see if Ifenprodil could help in the world's fight against COVID-19", said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. "We look forward to completing our data review and receiving feedback from the U.S. FDA."

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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