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Algernon Pharmaceuticals Announces Database Lock in Phase 2 Study of IPF and Chronic Cough

VANCOUVER, British Columbia, June 13, 2022 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the “Company” or “Algernon”) (CSE: AGN) (FRANKFURT: AGWO) (OTCQB: AGNPF) a clinical stage pharmaceutical development company is pleased to announce that its Phase 2 proof-of-concept study of NP-120 (“Ifenprodil”) for idiopathic pulmonary fibrosis (“IPF”) and chronic cough has reached database lock. This means that all data from the trial is now finally reported, cleaned and "locked" in the database. As previously stated, the Company is projecting that topline data will be available in July, 2022.

The study began in 2020, and recruited patients in Australia and New Zealand with an established diagnosis of IPF and a persistent cough. Recruitment ended in February, 2022, when 20 patients had been enrolled.

Phase 2 Study Summary

The purpose of this proof-of-concept Phase 2 human trial is to determine the safety and efficacy of Ifenprodil in patients with IPF and its associated cough.

In this open label, single-arm study, 20 patients were enrolled that had a diagnosis of IPF and a self-described moderate or worse cough (a score of >40mm on a cough visual analogue scale). Patients were treated with Ifenprodil (20 mg TID) for 12 weeks.

The primary endpoint of the IPF portion of the study is the proportion of patients who achieve zero reduction in lung function at 12 weeks vs. baseline. Lung function was measured by forced vital capacity (“FVC”).

The primary endpoint of the chronic cough portion of the study is a 50% reduction in average 24-hour cough count at 12 weeks vs. baseline. Cough counts were recorded using an ambulatory cough monitor.

However, based on data seen in recent IPF and chronic cough trials from other companies, Algernon will also perform a pre-specified subgroup analysis on patients with higher baseline cough counts. In addition, the Company will also measure the proportion of patients with a less than 2.5% reduction in FVC.

In addition to safety and tolerability, the effect on serum biomarkers of fibrosis will also be reported including proC3, C3M, proC5, C5M, proC6, C6M and reC1M.

About Ifenprodil

Ifenprodil is an N-methyl-D-aspartate (NMDA) receptor antagonist specifically targeting the NMDA-type subunit 2B (GluN2B). Ifenprodil prevents glutamate signalling. The NMDA

receptor is found on many tissues including lung cells, T-cells, and neutrophils.

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 intellectual property rights globally for Ifenprodil for the treatment of respiratory diseases.

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Source: Algernon Pharmaceuticals