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Algernon Pharmaceuticals Announces Plans for a Phase 2 Ifenprodil Chronic Cough Study in the U.S.

VANCOUVER, British Columbia, Sept. 20, 2021 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (CSE: AGN) (OTCQB: AGNPF) (FRANKFURT: AGW) (the "Company" or "Algernon") a clinical stage pharmaceutical development company, is pleased to announce that it plans to file a pre-IND (Investigational New Drug) meeting request with the U.S. Food and Drug Administration (U.S. FDA) for an NP-120 (Ifenprodil) Phase 2 chronic cough study. Ifenprodil is an N-methyl-D-aspartate (NMDA) receptor antagonist specifically targeting the NMDA-type subunit 2B (GluN2B).

The decision to expand its Ifenprodil research program was based on positive trending interim data received by the Company from the chronic cough part of its 20-patient Phase 2 idiopathic pulmonary fibrosis (IPF) and chronic cough study being conducted in Australia and New Zealand. The interim analysis examined 24-hour and waking cough counts measured using an ambulatory cough monitor at baseline and after 4 and 12 weeks of treatment with Ifenprodil, 20 mg three times daily. The data showed a trend to a relative reduction in cough count when compared to each patient's baseline measurement control.

The Company's pilot IPF and chronic cough Phase 2 trial was neither powered nor intended to show statistical significance but was designed to identify signals and the magnitude of any clinical effects. While chronic cough is a symptom which occurs in a subset of patients with IPF, it is often severe and difficult to treat in IPF patients compared to chronic cough arising from other causes. Typically, IPF patients are excluded from clinical trials in chronic cough patients. A relative reduction of cough count in these patients is being viewed by the Company as encouraging news.

The new planned Phase 2 study will be solely focussed on chronic cough patients, will be powered to ensure statistical significance, and will also have a placebo control. The planned Phase 2 clinical trial will also take into consideration the recent study designs of other chronic cough clinical trials including focussing on patients who have a more frequent cough. The Company has decided to seek guidance from the U.S. FDA for a Phase 2 study as its next step, having evaluated Ifenprodil's safety profile in its 150-patient multinational study for COVID-19.

"We believe that Ifenprodil represents a potential novel *first-in-class* treatment for chronic cough," said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. "We will update the market when we have filed the pre-IND meeting request and look forward to receiving feedback from the U.S. FDA in due course."

About Chronic Cough

A chronic (persistent) cough is a cough lasting eight weeks or longer in adults, or four weeks in children. Chronic cough can interrupt sleep, cause exhaustion and in severe cases can cause serious vomiting, light-headedness and rib fractures.

According to IndustryARC™ the cough remedies market size is estimated to be $1.40B, in 2018, growing at a CAGR of 6.64% during 2019-2024. Pleasant taste and easy intake of oral syrups are among the key factors driving the global cough remedies market.

About NP-120 (Ifenprodil)

NP-120 (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. Ifenprodil has no known taste disturbance.

About Algernon Pharmaceuticals Inc.

Algernon is a drug re-purposing company that investigates safe, already approved drugs, and 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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