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Algernon Pharmaceuticals Receives U.S. FDA Orphan Drug Designation for Ifenprodil for the Treatment of Idiopathic Pulmonary Fibrosis

VANCOUVER, British Columbia, Dec. 05, 2022 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the "Company" or "Algernon") (CSE: AGN) (FRANKFURT: AGW0) (OTCQB: AGNPF), a Canadian clinical stage pharmaceutical development company, is pleased to announce that the United States Food and Drug Administration ("U.S. FDA") has granted Orphan Drug Designation (ODD) to Ifenprodil as a treatment for Idiopathic Pulmonary Fibrosis (IPF). Ifenprodil is the sole active ingredient in NP-120, an NMDA receptor antagonist and the Company's lead clinical candidate being developed for the treatment of IPF and chronic cough.

The Company recently concluded a Phase 2a study of Ifenprodil in patients with IPF. The trial met its co-primary IPF endpoint with patients receiving Ifenprodil experiencing no worsening of their lung function, and significant improvements were seen in the frequency of their IPF-associated cough as well. In addition, improvements in patient-reported measures of cough severity and quality of life were observed. Ifenprodil was also confirmed to be safe and well-tolerated in the study.

Supporting the development and evaluation of new treatments for rare diseases through ODD is a priority for the U.S FDA and other jurisdictions including Europe, that have similar orphan programs. The designation is available only for rare diseases, defined by the U.S. FDA as those which affect fewer than 200,000 patients in the United States. ODD qualifies sponsors for incentives including tax credits for qualified clinical trials and an exemption from user fees. If a product receiving ODD is subsequently granted approval, it receives seven years of market exclusivity, meaning that the U.S FDA may not approve any other applications, including a full New Drug Application, for the same product in the same indication.

"We appreciate the U.S. FDA's decision to grant ODD status to Ifenprodil for IPF, a disease for which prognosis remains dismal, with 50% mortality expected within 3-4 years," said Christopher J. Moreau, CEO of Algernon. "This regulatory milestone comes at an important time in the development of Ifenprodil as a potential new therapy for IPF, as we plan the next steps for our clinical program."

About IPF

IPF is a type of chronic lung condition characterized by a progressive and irreversible decline in lung function and scarring (fibrosis) of the lungs. There is no cure for IPF and there are currently no procedures or medications that can remove the scarring from the lungs. At least 70%-85% of patients with IPF are additionally affected by a dry non-productive cough, which

can often get worse on exertion.

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. Ifenprodil represents a novel first in class treatment for both IPF and chronic cough.

About Algernon Pharmaceuticals Inc.

Algernon is a Canadian clinical stage drug development company investigating multiple drugs for unmet global medical needs. Algernon has active research programs for IPF with chronic cough, chronic kidney disease, and a psychedelic program investigating a proprietary form of DMT for stroke.

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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.

Source: Algernon Pharmaceuticals