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Algernon Pharmaceuticals Files for Orphan Designation with the U.S. FDA for Ifenprodil as a Treatment of IPF

VANCOUVER, British Columbia, Sept. 19, 2022 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the "Company" or "Algernon") (CSE: AGN) (FRANKFURT: AGW0) (OTCQB: AGNPF) a clinical stage pharmaceutical development company is pleased to announce that it has decided to advance its investigation of NP-120 (Ifenprodil) for IPF with cough as its key indication. As a result, the Company further announces it has filed a request for Orphan Designation with the United States Food and Drug Administration ("U.S. FDA") for the use of Ifenprodil as a treatment for IPF.

Supporting the development and evaluation of new treatments for rare diseases through orphan designation is a priority for the U.S. FDA and other jurisdictions (Europe) that have similar orphan programs. Orphan designation qualifies sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees, and a potential seven years of market exclusivity after approval. 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, which the Company's research indicates that IPF may qualify.

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 affected by a dry non-productive cough, which can often get worse on exertion.

The Company has decided to focus on the continued investigation of Ifenprodil for IPF with cough after hitting its key co-primary endpoint in its Phase 2a study of IPF with chronic cough. In the trial, patients receiving Ifenprodil experienced no worsening of their lung function, and significant improvements in the frequency of their IPF-associated cough. In addition, improvements in patient-reported measures of cough severity and quality of life were observed. The drug was also confirmed to be safe and well tolerated in the study.

"The outlook for patients with IPF remains dismal, with 50% mortality expected within 3-4 years, and so new treatments are desperately needed," said Christopher J. Moreau CEO of Algernon. "Algernon will continue working to accelerate the development of Ifenprodil as a potential new therapy for IPF with cough."

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 with global unmet 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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Source: Algernon Pharmaceuticals