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Algernon Pharmaceuticals Announces Positive Feedback from U.S. FDA for Phase 1 Ifenprodil Small Cell Lung Cancer Study

VANCOUVER, British Columbia, Nov. 24, 2021 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the "Company" or "Algernon") (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) a clinical stage pharmaceutical development company, is pleased to announce that it has received positive feedback from the U.S. Food and Drug Administration (U.S. FDA) at its pre-IND (Investigational New Drug) meeting for its investigation of NP-120 (Ifenprodil) for the treatment of small cell lung cancer (SCLC). Ifenprodil is an N-methyl-D-aspartate (NMDA) receptor antagonist specifically targeting the NMDA-type subunit 2B (GluN2B).

As a result of the feedback, the Company is not planning to conduct any additional pre-clinical research and will immediately move to file an IND application to begin its Phase 1 SCLC study as soon as possible. Based on the feedback from the meeting, the Company plans to use its current Ifenprodil finished product inventory for the study. The U.S. FDA meeting also produced very helpful guidance on the protocol design and endpoints for the planned SCLC study.

The Company is planning to conduct its Phase 1 study in patients with recurrent SCLC and, as a result, preliminary efficacy signals may be observed in the data.

The Company also plans to apply for orphan drug designation for Ifenprodil to treat patients with SCLC. The U.S. Orphan Drug Act grants special status to a drug for the treatment, diagnosis or prevention of a rare disease or condition.

The Company's decision to investigate Ifenprodil and move it into human trials for SCLC is based on a preclinical study, authored by Dr. William North, and published in January 2019, entitled, "Small-Cell Lung Cancer Growth Inhibition: Synergism Between NMDA Receptor Blockade and Chemotherapy". In the study, Ifenprodil, in combination with chemotherapeutic agent Topotecan, produced clear additive effects that significantly blocked tumor growth.

In August 2021, Algernon announced that it had signed an exclusive licensing agreement with Dartmouth College to acquire the rights to a method of use patent for treating neuroendocrine cancers, which express functional NMDA receptors. The Company also announced it appointed Dr. William North, professor emeritus at Dartmouth College and cancer research pioneer, as lead consultant.

In addition, based on the positive feedback from this Pre-IND meeting, the Company is also planning to file a Pre-IND meeting request for Ifenprodil and the investigation of pancreatic cancer in a Phase 1 study.

"We are very pleased with the response we received from the U.S. FDA," said Christopher J. Moreau CEO of Algernon Pharmaceuticals Inc. "Being able to move directly into a SCLC Phase 1 study will save the Company considerable cost and time and will allow us to more quickly begin investigating Ifenprodil as a potential non-toxic cancer treatment option for patients who suffer from this disease."

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 and certain types of cancer cells.

About Algernon Pharmaceuticals Inc.

Algernon is a drug re-purposing company that investigates safe, 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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