ALGERNON ANNOUNCES FILING OF U.S. FDA PRE-IND MEETING REQUEST FOR IFENPRODIL CORONAVIRUS TRIAL, EXPANDED ACCESS, AND EMERGENCY USE

VANCOUVER, British Columbia, March 13, 2020 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) (the "**Company**" or "**Algernon**") a clinical stage pharmaceutical development company is pleased to announce that is has filed its pre-IND (Investigational New Drug) meeting request with the U.S. FDA. This initiates formal communications with the U.S. FDA regarding development of the Company's repurposed drug NP-120 (Ifenprodil) for the treatment and prevention of acute lung injury (ALI) and acute respiratory distress syndrome associated with COVID-19 (coronavirus) infection. The request for a pre-IND meeting was accompanied by the complete pre-IND briefing document.

In the application, the Company has requested direction regarding the use of Algernon's planned new propriety injectable and slow release formulation as well as the use of the Company's currently available Ifenprodil drug supply, for a US clinical trial on an emergency use basis. This filing also includes clarification of the expanded access pathway, also known as the "compassionate use" pathway.

The decision to file with the U.S. FDA, was made after a recent independent study found that Ifenprodil significantly reduced ALI and improved survivability in an animal study with Asian H5N1 infected mice by 40%. Asian H5N1 is the most lethal form of influenza known to date with an over 50% mortality rate. The drug was also previously shown in a separate study to prolong survival under anoxic (low oxygen) conditions, as might occur in patients with severely impaired lung function.

Ifenprodil H5N1 Animal Study Background:

A genome wide RNAi interference approach to identify genes that aid in the recovery of cell viability after H5N1 infection, lead to the identification of the NMDA receptor antagonist Ifenprodil, which when tested in an animal model of H5N1 infection showed:

1. Markedly decreased leukocyte infiltration and lung injury scores in effected lungs
2. Significantly ameliorated edema infected mouse lung tissue
3. Significantly improved the survival of H5N1 infected mice by 40%

Study Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6906739/

“This is a very important step for the Company as we move forward on our strong belief, based on the data, that NP-120 (Ifenprodil) may be an effective treatment for coronavirus (COVID-19),” said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. “I would like to thank the entire Algernon team for all of the hard work and dedication this past week that went into preparing our pre-IND application. We will update the market shortly on the direction we receive from the U.S. FDA and based on circumstances, we are hoping for an expedited response.”

About NP-120 (Ifenprodil)

NP-120 (Ifenprodil) is an N-methyl-d-aspartate (NDMA) receptor glutamate receptor antagonist specifically targeting the NMDA-type subunit 2B (Glu2NB). Ifenprodil also exhibits agonist activity for the Sigma-1 receptor, a chaperone protein up-regulated during endoplasmic reticulum stress. Although the anti-fibrotic activity of Ifenprodil in IPF is not known, recent studies have suggested a link between both receptors and pathways associated with fibrosis.

Glutamate (Glu) is the main excitatory neurotransmitter which acts on glutamate receptors in the central nervous system (CNS) but overactivation of these receptors can cause several damages to neural cells including death. Recent studies show that the glutamate agonist N-methyl-d-aspartate (NMDA) can trigger acute lung injury (ALI). ALI is a direct and indirect injury to alveolar epithelial cells and capillary endothelial cell, causing diffuse pulmonary interstitial and alveolar edema and acute hypoxic respiration failure. ALI is characterized by reduced lung volume and compliance, and imbalance of the ventilation/perfusion ratio, inducing hypoxemia and respiratory distress and its severe stage (oxygen index <200) known as acute respiratory distress syndrome (ARDS). (1) Furthermore, pathological findings show that 64% of ARDS patients may have pulmonary fibrosis during convalescence (2).

NP-120 (Ifenprodil) was initially developed by Sanofi in the 1970’s in the French and Japanese markets for the treatment of circulatory disorders. The drug is genericized and sold in Japan and South Korea and is used to treat certain neurological conditions.

About Algernon Pharmaceuticals Inc.

Algernon Pharmaceuticals is a clinical stage pharmaceutical development company focused on advancing its lead compounds for non–alcoholic steatohepatitis (NASH), chronic kidney disease (CKD) inflammatory bowel disease (IBD), idiopathic pulmonary fibrosis (IPF) and chronic cough.

Algernon has filed new intellectual property rights for NP-120 (Ifenprodil) for the treatment of respiratory diseases and is working to develop a proprietary injectable and slow release formulation.

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(1) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5938426/
(2) https://www.ncbi.nlm.nih.gov/pubmed/19909524