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Algernon Provides an Overview of its NP-120 (Ifenprodil) Program for COVID-19

VANCOUVER, British Columbia, March 24, 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 provide an overview of its multiple recent activities surrounding the investigation of its repurposed drug compound NP-120 (Ifenprodil), as a possible treatment for idiopathic pulmonary fibrosis (IPF), acute lung injury (ALI), chronic cough, and coronavirus (COVID-19).

Background

- Algernon is a drug re-purposing company that investigates safe, already approved drugs 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.
- One of the drugs Algernon has been investigating is a generic Sanofi neurological drug developed in the 1970's called Ifenprodil, which is currently approved for use in South Korea and Japan.
- Algernon investigated Ifenprodil for IPF, which outperformed the world's leading two IPF treatments Nintedanib and Pirfenidone, in a pre-clinical *in vivo* animal study, reducing fibrosis by 56% with statistical significance.
- Ifenprodil also outperformed Merck's phase 3 drug Gefapixant in a recent acute cough animal study by 110%.
- The Company intends to submit for ethics approval for a phase 2 clinical trial for Ifenprodil for IPF and chronic cough in Australia shortly.
- An independent study found that Ifenprodil significantly reduced ALI and improved survivability in an animal study with Avian H5N1 infected mice by 40% (as a result Algernon has decided to expand its Ifenprodil clinical program to include ALI and COVID-19 – read more below). Avian H5N1 is the most lethal form of influenza known to man with an over 50% mortality rate.
- Ifenprodil was also shown in a separate independently published *in vivo* study to prolong survival under anoxic (low oxygen) conditions, as might occur in patients with severely impaired lung function.

Update on Algernon's Response to the COVID-19 Pandemic

The Company continues to develop Ifenprodil for IPF and chronic cough. However, as a result of the data from an independent study showing the drug's performance in an animal study for H5N1, the Company has decided to expand its Ifenprodil clinical trial program to include ALI, a specific form of injury with diverse causes including influenza related pneumonia, and COVID-19.

Recent Algernon COVID-19 Initiatives:

1. **March 13, 2020** – Algernon Filed a pre-IND (Investigational New Drug) meeting request with the U.S. FDA for the treatment and prevention of ALI and acute respiratory distress syndrome (ARDS) associated with COVID-19 infection.
2. **March 13, 2020** - Algernon Contacts Gates Foundation Regarding Funding for the development of New COVID-19 Treatments.
3. **March 19, 2020** - Algernon announces support of a physician initiated planned Phase 2 trial of Ifenprodil for COVID-19 in South Korea.
4. **March 20, 2020** - Algernon appoints award winning Novotech as the contract research organization ("CRO") for a planned physician initiated study of Ifenprodil for COVID-19 patients in South Korea.
5. **March 20, 2020** - Algernon retains Novotech to conduct a feasibility study in Australia for a phase 2 sponsor initiated Ifenprodil COVID-19 trial. Novotech has already identified 3 physicians who have indicated their interest to participate.
6. **March 23, 2020** - Algernon appoints U.S. Based Cascade Chemistry to support its quickly evolving clinical program for ALI, its urgent clinical focus on COVID-19 as well as its idiopathic pulmonary fibrosis (IPF) and chronic cough clinical program.

Summary

The Company remains confident that Ifenprodil, an approved drug in Japan and South Korea with a known, strong safety history, has demonstrated evidence it may be protective of the lung by reducing the damage that can be caused by ALI.

As a result, Algernon believes its potential as a re-purposed drug for utilization in immediate phase 2 clinical trials by researchers for the treatment of COVID-19 is clear and significant.

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 only 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 globally 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>



Source: Algeron Pharmaceuticals