ALGERNON SUBMITS APPLICATION TO HEALTH CANADA FOR IFENPRODIL COVID-19 PHASE 2B/3 MULTINATIONAL CLINICAL TRIAL

VANCOUVER, British Columbia, April 22, 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 it has submitted a Clinical Trial Application (CTA) to Health Canada for an NP-120 (Ifenprodil) COVID-19 Phase 2b/3 multinational clinical trial. The same study protocol is being prepared for submission to the U.S. FDA and Australian regulatory authorities.

The study will be an adaptive pilot to pivotal trial design based on guidance documents from the World Health Organization (WHO) to determine if Ifenprodil can improve clinical symptoms and reduce the number of COVID-19 infected patients from progressing to mechanical ventilation with intubation and death.

The trial will begin as a Phase 2b study and after an interim analysis is performed on the first 100 patients, the data will determine the number of expected patients needed to reach statistical significance in a Phase 3 trial. With positive preliminary data, the clinical trial would move directly from a Phase 2b into a Phase 3 without the time delay involved in having to submit a new Clinical Trial Application.

"We are very excited about having the potential opportunity to transition this Ifenprodil COVID-19 trial into a Phase 3 study based on positive preliminary data," said Christopher J. Moreau CEO of Algernon. "Pending approval, we would be included with only a small handful of companies globally working with a potential drug treatment at a Phase 3 level on this disease."

The Company cautions that it is in the early stages of clinical research and development and is not making any express or implied claims that NP-120 (Ifenprodil) is an effective treatment for acute lung injury (ALI), the COVID-19 virus, or any other medical condition at this time.

Phase 2b/3 Study Protocol Overview

The trial will begin as a Phase 2b study enrolling 100 patients with moderate/severe disease, which corresponds with a score of 4 or 5 on the WHO ordinal clinical scale. Patients will be randomized in a 1:1 fashion to receive either standard of care (SOC) or SOC and Ifenprodil (20 mg three times per day) for a two-week treatment period. An improvement in the ordinal clinical scale is the initial primary endpoint and a number of secondary endpoints including mortality, blood oxygen levels, time in the ICU and time to mechanical ventilation will be studied.

About NP-120 (Ifenprodil)

NP-120 (Ifenprodil) is an N-methyl-D-aspartate (NMDA) receptor antagonist specifically targeting the NMDA-type subunit 2B (Glu2NB). Ifenprodil prevents glutamate signalling. The NMDA receptor is found on many tissues including lung cells and T-cells, neutrophils.

The Company believes NP-120 can reduce the infiltration of neutrophils and T-cells into the lungs where they can release glutamate and cytokines respectively. The latter can result in the highly problematic cytokine storm that contributes to the loss of lung function and ultimately death as has been reported in COVID-19 infected patients.

About Algernon Pharmaceuticals Inc.

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.

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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