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Algernon Pharmaceuticals Reports Positive Results from Full Data Set of its Phase 2 Study of Ifenprodil for IPF and Chronic Cough

VANCOUVER, British Columbia, Sept. 01, 2022 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the "Company" or "Algernon") (CSE: AGN) (FRANKFURT: AGW0) (OTCQB: AGNPF) a clinical stage Canadian pharmaceutical development company, is pleased to report positive results from the full data set of its Phase 2a Study evaluating NP-120 ("Ifenprodil") for the potential treatment of idiopathic pulmonary fibrosis ("IPF") and chronic cough.

The full data set includes additional secondary measures of efficacy, including both objective measurement of lung function and patient-reported outcomes of both IPF and cough. All of the data showed positive results, including statistically significant improvements in measures of cough.

On July 18th, the company announced top line data indicating that the study's IPF co-primary endpoint, preservation of lung function determined by no worsening of forced vital capacity ("FVC") over 12 weeks, had been met. The Company further reported on July 28th, significant reductions in geometric mean cough counts after both 4 and 12 weeks of treatment.

IPF Data

Secondary endpoints focused on pulmonary fibrosis, as indicated by key measures, were consistent with the preservation of lung function as measured by key indications, specifically:

- Unchanged diffusing capacity for carbon monoxide (DLCO) over twelve weeks (change from baseline 0.00, $p > 0.99$, 95% CI -3.14, 3.14). DLCO estimates the ability of the lungs to transfer oxygen between alveolar gas and red blood cells.
- No change in the modified Medical Research Council (mMRC) dyspnea scale over twelve weeks. The mMRC scale is a self-rating tool to measure the degree of disability imposed by breathlessness on day-to-day activities.
- An increase of 7.0 points in the King's Brief Interstitial Lung Disease Questionnaire (K-BILD) ($p = 0.1209$, 95% CI -2.03, 16.03). The K-BILD is a self-administered health-status questionnaire developed in patients with interstitial lung diseases (higher scores are better).

Cough Data

Secondary endpoints focused on cough showed significant improvements, namely:

- A reduction of 23.6 mm from baseline in the cough visual analogue scale (VAS) (p = 0.0005, 95% CI -35.22, -11.94). The cough VAS is a patient-reported subjective assessment of cough severity (lower scores are better).
- An improvement of 10.05 points in the mean score on the Leicester Cough Questionnaire (LCQ) (p = 0.0296, 95% CI 1.12, 18.99). The LCQ is a self-completed quality of life measure of chronic cough (higher scores are better).

Ifenprodil was well tolerated with a high overall compliance rate (average >90%). As reported with the top line data, no new safety concerns were identified.

The full results of the trial will be presented at the 21st International Colloquium on Lung and Airway Fibrosis in Reykjavik, Iceland in October 2022, and will also be discussed at the 9th American Cough Conference in Reston, Virginia in June 2023.

“The full data set is excellent,” said Dr. Martin Kolb, professor of respirology at McMaster University and global expert on IPF. “Of course, patient numbers are low, but it is encouraging to see that all is going in the right direction. This data enhances my belief that this drug merits investigation in a much larger trial.”

“This data, when added to the topline data already reported, now provides a more complete picture that shows just how effective Ifenprodil was in this Phase 2a study,” said Christopher J. Moreau CEO of Algernon. “We look forward to presenting the data to the U.S FDA, including applying for orphan designation, the filing of a pre-IND application for a Phase 2b IPF with cough trial, as well as an application for Breakthrough Therapy designation.”

The Company also announces a grant of 221,000 restricted share units pursuant to its RSU Plan (each, an "RSU") to executives, directors, employees and consultants of the Company. Each RSU entitles the recipient to receive one common share of the Company or a cash payment equal to the equivalent for one common share of the Company on vesting. The RSUs vest one-third on January 1, 2023, one-third on June 1, 2023, and one-third on January 1, 2024.

The Company has also granted 92,000 stock options exercisable at $5.39 for five years from date of grant, to officers, directors, employees and consultants of the Company. The stock options vest 50% on the grant date and 50% on February 28, 2023.

The RSUs and stock options are subject to approval by regulatory authorities.

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 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.

CONTACT INFORMATION

Christopher J. Moreau
CEO
Algernon Pharmaceuticals Inc.
604.398.4175 ext 701

info@algernonpharmaceuticals.com
investors@algernonpharmaceuticals.com
www.algernonpharmaceuticals.com

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