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Algernon Pharmaceuticals Announces Positive Feedback from U.S. FDA for Phase 2b Ifenprodil Chronic Cough Study

VANCOUVER, British Columbia, Jan. 14, 2022 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the "Company" or "Algernon") (CSE: AGN) (FRANKFURT: AGW0) (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-Investigational New Drug (pre-IND) meeting for its investigation of NP-120 (Ifenprodil) for the treatment of chronic cough. Ifenprodil is an N-methyl-D-aspartate (NMDA) receptor antagonist specifically targeting the NMDA-type subunit 2B (GluN2B).

The U.S. FDA meeting produced helpful guidance on the Phase 2b protocol design that was submitted by the Company as well as the endpoints that had been selected. The U.S. FDA also requested standard genotoxicity testing be completed prior to beginning the Phase 2b study, which the Company estimates will take approximately 90 days to complete.

The Company filed the pre-IND meeting request to seek guidance in the event the Company decides to move forward with a chronic cough Phase 2b study in the U.S. On September 20, 2021, the Company reported positive trending interim data from the chronic cough part of its 20-patient proof-of-concept Phase 2 idiopathic pulmonary fibrosis (IPF) and chronic cough study being conducted in Australia and New Zealand.

The interim analysis examined 24-hour and waking cough counts measured using an ambulatory cough monitor at baseline and after 4 and 12 weeks of treatment with Ifenprodil, 20 mg three times daily. The data showed a trend to a relative reduction in cough count when compared to each patient's baseline measurement control.

"We are very pleased with the response we received from the U.S. FDA," said Christopher J. Moreau CEO of Algernon Pharmaceuticals Inc. "We look forward to the final data set from our IPF and chronic cough study so that we can plan our next steps."

Ifenprodil Pre-Clinical Cough Data

In Algernon's pre-clinical animal cough study, Ifenprodil showed both a dramatic reduction in cough count and a delay in cough onset when compared to vehicle controls in a well-accepted acute cough *in-vivo* animal study. **Gefapixant**, Merck's lead phase 3 trial drug for chronic cough, was also tested in the study.

Pharmidex, a contract research organization (CRO) and a global leader in respiratory research conducted the *in-vivo* cough study using the guinea pig citric acid challenge model. Data from this study demonstrated that at clinically relevant doses:

- Ifenprodil (1.5 mg/kg) showed a reduction of 42% in mean cough frequency vs. untreated control ($p < 0.01$).
- Gefapixant (3.5 mg/kg) showed a 20% reduction in mean cough frequency vs. untreated control ($p < 0.05$).
- Ifenprodil (59.8 seconds) showed a statistically significant delay in the onset of the first cough when compared to control (34.2 seconds, $p < 0.05$). Gefapixant (49.7 seconds) also showed a numerical reduction in cough onset, but the difference was not significant.

Additional Information:

- Unlike Gefapixant, **Ifenprodil** has no known taste disturbance, which is a similar benefit to Bellus Health's Phase 2 asset BLU-5937.
- The Company previously reported that Ifenprodil was anti-fibrotic in a bleomycin mouse model of IPF, outperforming both Roche's drug Pirfenidone and Boehringer Ingelheim's drug Nintedanib.

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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