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Algernon Pharmaceuticals Reports Results of Study Showing 93% Cough Suppression with Ifenprodil

VANCOUVER, British Columbia, July 16, 2024 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) (the "Company" or "Algernon") a clinical stage pharmaceutical development company, is pleased to report that ifenprodil achieved a 93% ($p = 0.036$) reduction in median cough count in an acute guinea pig citric acid challenge study.

The multi-dose study was conducted under the direction of Seyltx, Inc. ("Seyltx"), a private US-based drug development company which recently acquired Algernon's ifenprodil research program for the purchase price of $2M USD and a 20% equity position. The study was designed to inform dose selection in Seyltx's planned Phase 2b ifenprodil human study, recently named SILINDA, in refractory chronic cough ("RCC"). Seyltx has also announced that patient enrollment in the study is expected to begin in early 2025.

Ifenprodil is an N-methyl-D-aspartate (NMDA) receptor antagonist specifically targeting the NR2B subunit, which prevents glutamate signalling. Ifenprodil represents a first-in-class potential treatment for chronic cough and interferes with central signalling in the brain, supressing the urge to cough.

The near-complete suppression of cough was observed in animals receiving a dose of 30 mg/kg, in a dose-dependent manner, below the no observed adverse effect level dose ("NOAEL"). Other dosing arms included 1, 3, and 10 mg/kg. A clear and statistically significant dose response was observed. The full results of the study will be presented at the London International Cough Symposium July 18th – 19th, 2024.

In an earlier Algernon Phase 2a clinical trial measuring cough in patients with idiopathic pulmonary fibrosis, ifenprodil, 20 mg TID (three times daily), reduced cough by ~40% from baseline ($p = 0.001$).

"The successful completion of this pre-clinical dose-ranging study, together with our human Phase 2a efficacy data, validates the target as a central node in this pathogenic process and informs our dosing regimen for our upcoming Phase 2b trial in RCC," commented Dietrich A. Stephan, Ph.D., CEO of Seyltx. "We are now well positioned to execute our SILINDA Phase 2b program, and we look forward enrolling our first patient in early 2025."

"The dramatic cough suppression effects observed occur below the NOAEL dose and with no apparent impact on overall respiration," commented Brendan Canning, Ph.D., Professor of Medicine at Johns Hopkins University School of Medicine, and a member of the Seyltx Scientific Advisory Board. "These data give us confidence in ifenprodil's potential to be a best-in-class treatment option for RCC patients."

“We plan to incorporate all of the recent learnings related to topics such as optimal placebo run-in and clinical endpoints to maximize SILINDA’s probability of success,” said Jacky Smith, MB, ChB, FRCP, Ph.D., professor of respiratory medicine at the University of Manchester and a member of the Seyltx Scientific Advisory Board. “Given the effect sizes we are seeing, the potential to work across a broad patient population, and the uniqueness of the target, this product candidate could benefit millions of patients suffering with this untreatable disorder.”

SILINDA Phase 2b Study Summary

Based on U.S. FDA feedback, Seyltx’s SILINDA program is currently structured to include three dose arms and a placebo arm, evaluating the efficacy, safety, and tolerability of ifenprodil in approximately 240 adults with RCC. SILINDA will be placebo-controlled, parallel-arm trial randomized 1:1:1:1 with expected treatment arms of 40 mg TID, 80 mg TID, 120 mg TID, and placebo. The primary endpoint of 24-hour cough frequency will be measured at 12-weeks.

The SILINDA Phase 2b program’s primary endpoint will be assessed using the VitaloJAK® cough monitoring system in a patient population that is not stratified for baseline 24-hour cough frequency given the uniform efficacy seen in the Phase 2a open label study across both low and high cough count patients. Key exploratory efficacy endpoints include the Cough Severity using Visual Analogue Scale (“CS-VAS”), the Leicester Cough Questionnaire (“LCQ”) and real-time longitudinal cough monitoring. Topline data from SILINDA are expected at the end of 2026.

For more information about the Seyltx ifenprodil guinea pig citric acid challenge study click here: https://www.seyltx.com/media-center

About Algernon Pharmaceuticals Inc.

Algernon Pharmaceuticals is a Canadian clinical stage drug development company investigating multiple drugs for unmet global medical needs. Algernon Pharmaceuticals is the parent company of a private subsidiary called Algernon NeuroScience, that is advancing a psychedelic program investigating a proprietary form of DMT for stroke and traumatic brain injury and has an active research program for chronic kidney disease.

Algernon recently announced that it closed on its agreement with Seyltx Inc., a privately owned U.S. based drug development company, for the acquisition of Algernon’s Ifenprodil research program for the purchase price of USD $2M cash and a 20% common share equity position in Seyltx. For more information: https://www.algernonpharmaceuticals.com

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