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Algernon Pharmaceuticals Announces Closing of the Acquisition of its Chronic Cough Research Program by U.S. Based Seyltx for USD $2M and a 20% Equity Position

VANCOUVER, British Columbia, March 27, 2024 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the "Company" or "Algernon") (CSE: AGN) (FRANKFURT: AGW0) (OTCQB: AGNPF), a Canadian clinical stage pharmaceutical development company, is pleased to announce that it has closed on its agreement with Seyltx Inc. ("Seyltx"), a privately owned U.S. based drug development company, for the acquisition of Algernon's NP-120 ("Ifenprodil") research program for the purchase price of USD $2M cash and a 20% common share equity position in Seyltx. The Company previously announced on November 22, 2003 that it had signed a Letter of Intent with Seyltx, to acquire Algernon's Ifenprodil research program.

Ifenprodil is an N-methyl-D-aspartate ("NMDA") receptor antagonist specifically targeting the NMDA type subunit 2B (GluN2B), which prevents glutamate signaling. Ifenprodil is one of Algernon's lead research programs and represents a novel first-in-class potential treatment for chronic cough. It is thought to interfere with central signalling in the brain, suppressing the urge to cough.

"There are multiple converging lines of evidence that define GluN2B as the master regulator of the cough reflex in the deep brain, including human clinical data with the allosteric inhibitor Ifenprodil in the hardest to treat cough population, those with underlying idiopathic pulmonary fibrosis, illustrating dramatic reductions in cough counts. This human efficacy data is complemented by an extensive safety package that de-risks the final phases of clinical development," said Dietrich A. Stephan, Ph.D. co-founder and CEO of Seyltx. "I have great respect for the Algernon team who have done an outstanding job at maturing the program to this point, and we look forward to completing the clinical development of this exciting agent for a common and debilitating condition."

Seyltx plans to initiate an Ifenprodil multi-center Phase 2b placebo-controlled chronic cough study in CY2024. Algernon's clinical management team will be available to provide support, oversight, and management of the study.

"We are very pleased to have closed this transaction with Seyltx," said Christopher J. Moreau, Algernon's Chief Executive Officer. "We believe that Ifenprodil, a first in class potential treatment for chronic cough could outperform all other drugs that have been clinically investigated to date. We look forward to working with Seyltx as they advance Ifenprodil into the Phase 2b clinical trial."

In connection with the transaction, Maxim Group LLC was paid a transaction advisory services fee pursuant to an agreement with Algernon whereby Maxim was retained to identify and evaluate potential M&A and strategic opportunities.

Algernon's Phase 2a Study Data

Algernon's decision to advance to a Phase 2b cough study was based on positive data previously reported from the Company's proof of concept Phase 2a study of idiopathic pulmonary fibrosis ("IPF") and chronic cough, where Ifenprodil showed a significant reduction in cough count. Patients with IPF are usually excluded from trials in refractory chronic cough ("RCC"), and cough in this population is regarded as extremely difficult to treat.

Key Data:

- The geometric mean 24-hour cough counts were reduced by 32.0% at 4 weeks ($p = 0.023$) and 39.5% at 12 weeks ($p = 0.001$) compared to baseline
- The geometric mean awake cough counts were reduced by 30.2% at 4 weeks ($p = 0.038$) and 37.4% at 12 weeks ($p = 0.002$) compared to baseline
- Algernon previously announced on January 14, 2022, that it had received positive feedback from the U.S. Food and Drug Administration at its pre-Investigational New Drug (pre-IND) meeting for its investigation of Ifenprodil solely for the treatment of chronic cough.

About Chronic Cough

Chronic cough is defined as a cough lasting for more than eight weeks in duration and in the United States cough continues to be one of the most common reasons that adults consult medical doctors. Some cases of chronic cough are so debilitating that quality of life is severely impacted leading to depression, anxiety, urinary incontinence, dysphonia, sleep interruption, vomiting, and even rib fractures further adding to the decay in socio-familial dynamics.

Chronic cough is believed to be the result of a hypersensitivity of the cough reflex within the neuronal circuitry that governs the urge to cough, wherein one or more aspects that regulate cough are over-active to stimulus, triggering a cough at abnormal levels. Trials of cough suppressants ("Antitussives") have shown differences in response that may reflect differing pathological processes driving cough in different patients.

Experimental Antitussives (like gefapixant and camlipixant) often only engage a single receptor, while the overall cough response is governed by multiple receptors triggered by a large variety of stimuli. A compound like Ifenprodil, acting centrally in the brain where all peripheral messages are sent and coordinated, may achieve a better outcome than what has been achieved by others in clinical trials.

Chronic Cough Market

According to Data Bridge Market Research analyses, the global chronic cough market was valued at USD $6.15B in 2021 and is projected to grow up to USD $11.38B by 2029.

Merck & Co. obtained the rights to gefapixant, a $P2X_3$ receptor antagonist, as the lead asset in the acquisition of Afferent Pharmaceuticals in 2016. At the time, gefapixant had interim data from a Phase 2b study in RCC. The deal was worth up to USD $1.25 billion.

Bellus Health, which was advancing camlipixant, its own novel $P2X_3$ receptor antagonist, closed a deal on June 16, 2023 with GSK plc which bought all the outstanding shares in Bellus for USD $14.75 per share in cash with a total deal value estimated at USD $2 billion, confirming the need for better therapies for chronic cough.

About NP-120 (Ifenprodil)

NP-120 selectively inhibits GluN2B receptors which diminish excitability of neurons and prevent the relaying of information along neuronal circuitry, including the cough reflex. NP-120 may also inhibit the neuroplastic enhancement of central and peripheral cough response neurons.

About Seyltx Inc.

Seyltx is a clinical-stage pharmaceutical company focused on addressing refractory chronic cough by modulating the master switch of the cough reflex in the brain. Refractory chronic cough is a common disorder estimated to affect between 4-5 million individuals in the United States alone, for which there exist no effective therapies.

About Algernon Pharmaceuticals Inc.

Algernon Pharmaceuticals is a Canadian clinical stage drug development company investigating multiple drugs for unmet global medical needs. Algernon Pharmaceuticals has active research programs for chronic kidney disease and 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.

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Source: Algernon Pharmaceuticals Inc.