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

VANCOUVER, British Columbia, Nov. 22, 2023 (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 signed a Letter of Intent ("LOI") with Seyltx Inc. ("Seyltx"), a privately owned U.S. based drug development company, to acquire Algernon's NP-120 ("Ifenprodil") research program for USD $2M cash and a 20% common share equity position in Seyltx. The transaction is subject to certain conditions including, inter alia, Seyltx financing and the negotiation and execution of a definitive agreement, which is expected to occur within the next 90 days.

Seyltx plans to conduct an Ifenprodil Phase 2b chronic cough study as soon as possible. As stated in the LOI, Algernon's clinical management team will be available to provide support, oversight and management of the study.

Ifenprodil is an N-methyl-D-aspartate ("NMDA") receptor antagonist specifically targeting the NMDA type subunit 2B (GluN2B), which prevents glutamate signaling. Ifenprodil is Algernon's lead research program 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.

"We are very pleased to have signed this LOI with Seyltx," said Christopher J. Moreau, Algernon's Chief Executive Officer. "With the U.S. FDA advisory panel recently voting 12 – 1 against approving Merck's chronic cough drug candidate gefapixant, citing a lack of efficacy, it is very important to continue moving Ifenprodil forward as a potential global treatment of chronic cough."

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 acting centrally in the brain, like ifenprodil, 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 P2X3 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 P2X3 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 U.S.-based Delaware C-corporation focused on rapidly accelerating development of therapeutics that have established human safety and efficacy data. Seyltx is addressing underserved medical conditions that affect significant portions of the global population by selectively modulating neuronal receptors in the central nervous system that control pulmonary diseases.

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 IPF with chronic cough, and chronic kidney disease, and is the parent company of a newly created 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