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Algernon Pharmaceuticals Engages Maxim Group to Explore Spin-Off of its Ifenprodil Phase 2 Chronic Cough Drug Development Program

VANCOUVER, British Columbia, June 27, 2023 (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 engaged Maxim Group LLC (“Maxim”) to provide financial advisory and investment banking services, and to assist in identifying and evaluating potential M&A and strategic opportunities, including the potential spin-off of the Company’s NP-120 (“Ifenprodil”) chronic cough 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 represents a novel first-in-class potential treatment for chronic cough and is thought to interfere with central signaling in the brain, suppressing the urge to cough.

“We are very pleased to be working with Maxim, and we are especially interested in the potential to achieve significant value for our Ifenprodil asset and for our shareholders, through a spin-off transaction,” said Christopher J. Moreau, Algernon’s Chief Executive Officer. “Ifenprodil represents a novel first-in-class potential treatment for chronic cough, and we are only one Phase 2b study away from the stage of development where Bellus’ camlipixant was acquired by GSK and Afferent’s gefapixant was acquired by Merck.”

Algernon’s Phase 2a Study Data

The 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 on July 28, 2022, 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.

Further analysis revealed:

- 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.

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 dose-escalation study in RCC. The deal was worth up to USD \$1.25 billion.

Bellus Health, which is advancing camlipixant, its own novel P2X3 receptor antagonist, announced on April 18, 2023, that GSK plc signed a deal where they agreed to buy 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.

Algernon's Chronic Cough Advisors

Dr. Jacky Smith is a Professor of Respiratory Medicine at the University of Manchester and an Honorary Consultant at Manchester University NHS Foundation Trust. She runs a multi-disciplinary research team whose focus is on understanding mechanisms underlying pathological cough and a regional clinical service seeing patients with refractory chronic cough. Dr. Smith is also the lead medical and scientific advisor to both Merck and Bellus Health for their RCC research programs.

Dr. Peter Dicpinigaitis is board-certified in Internal Medicine, Pulmonary Diseases and Critical Care Medicine. He is a faculty member of the Division of Critical Care Medicine at Montefiore Medical Center and is the founder and director of the Montefiore Cough Center, one of the few specialty centers in the world exclusively committed to the evaluation and management of patients with 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 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, like ifenprodil, where all peripheral messages are sent and coordinated, may achieve a better outcome than what has been achieved in clinical trials.

About NP-120 (Ifenprodil)

Ifenprodil selectively inhibits N-methyl-D-aspartate (“NMDA”) receptors containing the NR2B subunit. They are highly implicated in events such as neuronal plasticity (strengthening of neural pathways) and excitotoxicity (neurotoxic cascade resulting in neuron death).

By inhibiting NMDA receptors, Ifenprodil can diminish excitability of neurons and prevent the relaying of information along neuronal circuitry, including the cough reflex. Ifenprodil may also inhibit the neuroplastic enhancement of central and peripheral cough response neurons.

About Maxim Group LLC

Founded in 2002, Maxim Group is a leading full-service investment bank, securities and wealth management firm headquartered in mid-town Manhattan providing a comprehensive array of financial services including investment banking, global institutional sales, equity research, fixed income and derivative sales & trading, merchant capital, private wealth management, and prime brokerage services to a diverse range of corporate clients, institutional investors and high-net-worth individuals. Maxim Group is a registered broker-dealer with the U.S. Securities and Exchange Commission and the Municipal Securities Rulemaking Board (MSRB).

About Algernon Pharmaceuticals

Algernon Pharmaceuticals is a Canadian clinical stage drug development and repurposing 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 psychedelic DMT for stroke and traumatic brain injury (“TBI”).

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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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Source: Algernon Pharmaceuticals