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Algeron Pharmaceuticals Submits U.S. FDA Pre-IND Meeting Request for Psychedelic Drug DMT Clinical Research Program for Stroke

VANCOUVER, British Columbia, March 17, 2021 (GLOBE NEWSWIRE) -- Algeron Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) (the "Company" or "Algeron"), a clinical stage pharmaceutical development company, is pleased to announce that it has filed a pre-IND (Investigational New Drug) meeting request with the U.S. FDA for its investigation of AP-188 ("N,N-Dimethyltryptamine or DMT"), a known psychedelic compound that is part of the tryptamine family, for the treatment of stroke-related dysfunction.

This initiates formal communications with the U.S. FDA regarding development of the Company's newly announced stroke clinical research program.

In the meeting request application, the Company is asking for direction regarding the use of DMT as an adjunctive treatment with constraint-induced movement therapy (CIMT) for the treatment of upper-limb dysfunction in stroke patients. Another pre-IND meeting request for the use of DMT as a treatment for acute stroke will be filed once the Company completes additional preclinical work.

CIMT is a form of physical therapy that involves intensive training of the weaker limb while restricting the use of the stronger limb, and has demonstrated the ability to enhance recovery in the treatment of patients post-stroke. The Company plans to evaluate whether adding DMT treatment to CIMT, results in increased neuroplasticity thereby enhancing the effects of physical therapy. CIMT is also used in the treatment of other movement disorders including traumatic brain injury, multiple sclerosis, and Parkinson's disease.

Algeron has filed new provisional patents for new forms of DMT, in addition to formulation, dosage and method of use claims for ischemic stroke. The Company has also filed claims for combination therapy of DMT and CIMT.

DMT – Building the Case for Stroke

The Company's decision to investigate DMT and move it into human trials for stroke is based on multiple independent, positive preclinical studies demonstrating that DMT helps promote neurogenesis, as well as structural and functional neural plasticity. These are key factors involved in the brain's ability to form and reorganize synaptic connections, which are needed for healing following a brain injury.

A recently published preclinical study in an animal model for stroke, showed that rats treated

with DMT recovered motor function more quickly and to a greater extent, and also exhibited lower lesion volumes when compared to control group animals that did not receive DMT. Key data from the study achieved statistical significance.

The full study can be viewed at the following link:

[DMT Preclinical Study](#)

The Company recently awarded the contract to manufacture the active pharmaceutical ingredient and finished product for its formulation of DMT, to Canadian-based Dalton Pharma Services. Algernon also recently retained Charles River Laboratories to conduct its preclinical studies of DMT for the Company's stroke clinical research program and additionally appointed the renowned contract UK based research organization Hammersmith Medicines Research Ltd, to conduct its DMT Phase 1 study.

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.

Algernon recently completed the Phase 2b part of a 150 patient Phase 2b/3 clinical trial of Ifenprodil for COVID-19 and has announced that it expects to report top line results in the last week of March 2021.

Algernon is also currently conducting a Phase 2 clinical trial of Ifenprodil for idiopathic pulmonary fibrosis and chronic cough in Australia and New Zealand.

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Source: Algernon Pharmaceuticals