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Algernon Files Meeting Request with MHRA for Use of DMT in Phase 1/2a Human Stroke Study

VANCOUVER, British Columbia, Oct. 13, 2021 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) (the "Company" or "Algernon") a clinical stage pharmaceutical development company, is pleased to announce that it has filed a scientific advice meeting request with the United Kingdom ("UK") Medicines and Healthcare Products Regulatory Agency ("MHRA") for a Phase 1/2a stroke study with AP-188 ("N,N-dimethyltryptamine" or "DMT"), a known psychedelic compound that is part of the tryptamine family.

The MHRA encourages companies to seek scientific advice before beginning clinical trials in the UK. These meetings are similar to the pre-IND meetings offered by the U.S. Food and Drug Administration. Through this process, the Company will confirm that its chemistry, manufacturing and controls information, pre-clinical data, and Phase 1/2a clinical plans are appropriate for submission of a Clinical Trial Authorisation (CTA) application for a study with DMT in the UK.

Submission of the CTA application is planned for Q4 of this year. The Phase 1 portion will investigate safety, dose, and the pharmacokinetics of DMT, while the Phase 2a part will additionally examine the use of DMT as an adjunctive treatment to Constraint-Induced Movement Therapy ("CIMT") for the treatment of upper-limb dysfunction in stroke patients.

During the Phase 1 study of DMT, the Company will also be able to evaluate if a sub hallucinogenic dose of DMT could be used for the treatment of hemorrhagic stroke patients in addition to patients who have suffered an ischemic stroke. This would be a significant discovery and could lead to a clinical trial to evaluate if patients would benefit from DMT shortly after their stroke has occurred.

The Company recently confirmed, in its own in vitro preclinical study, that DMT increased the growth of cortical neurons by 40% with statistical significance in one arm of the study, when compared to control. Algernon also reports that the increased growth was achieved with a sub hallucinogenic dose.

"We are pleased to initiate formal discussions of our clinical plans for DMT with the MHRA," said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. "The MHRA's familiarity with DMT means the agency is well-positioned to advise the Company on its clinical research program."

About DMT

N,N-Dimethyltryptamine, or DMT, is a hallucinogenic tryptamine drug producing effects similar to those of other psychedelics like LSD, ketamine, psilocybin and psilocin. DMT occurs naturally in many plant species and animals and has been used in religious ceremonies as a traditional spiritual medicine by indigenous people in the Amazonian basin. DMT can also be synthesised in a laboratory.

Algernon has filed 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.

About Algernon Pharmaceuticals Inc.

Algernon is a drug re-purposing company that investigates safe, already approved drugs, and 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.

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