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Algernon Pharmaceuticals Provides Update on Its Phase 1 DMT Stroke Study

VANCOUVER, British Columbia, July 07, 2022 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the “Company” or “Algernon”) (CSE: AGN) (FRANKFURT: AGW0) (OTCQB: AGNPF), a clinical stage Canadian pharmaceutical development company, is pleased to provide an update on its planned Phase 1 clinical human study of AP-188 (“N,N-dimethyltryptamine” or “DMT”). DMT is a known psychedelic compound that is part of the tryptamine family.

The Company is currently working to complete the intravenous formulation (“IVF”) that will be used in the Phase 1 DMT study and has retained the Centre for Human Drug Research (“CHDR”) and its affiliated pharmacy at the Leiden University Medical Center in the Netherlands, to complete the work. The Company is planning to begin the Phase 1 study in September of 2022.

The Company announced earlier that it had filed for a Clinical Trials of Investigational Medicinal Products (“CTIMP”) application with the United Kingdom Medicines and Healthcare Products Regulatory Agency (“UK MHRA”) via the combined review service, which provides for a single application route for both clinical trial authorization and ethics approval. The key feedback provided by the UK MHRA focussed on the IVF of DMT for administration.

The original plan was to complete the IVF in the onsite pharmacy at Hammersmith Medicines Research (HMR) in London, prior to the Phase 1 DMT study beginning. However, to meet the specifications requested by the UK MHRA, it was determined that a new vendor would be needed that had additional technical cGMP-suite capabilities.

After working to identify qualified vendors that could perform the needed work in the required time period, the Company selected CHDR and the IVF work is in progress. In addition to its fill finish cGMP-suite services, CHDR is also a world class clinical trial center, performing approximately 60 early-phase clinical studies per year.

The primary focus of Algernon’s planned Phase 1 DMT study is to investigate prolonged intravenous infusion of DMT, for durations which have never been clinically studied. The resulting data generated will help the Company to plan both its Phase 2 acute stroke and rehabilitation studies more effectively.

Phase 1 DMT Stroke Study Summary

The purpose of the planned study is to identify the safety, tolerability, and pharmacokinetics of DMT when administered as an intravenous bolus followed by prolonged infusion. The first part of the study will use a single-escalating dose design while the second part will test the effects of repeated administrations of the highest safe dose. There will be up to 60 healthy

volunteers enrolled across the two parts of the study which will include both psychedelic experienced and psychedelic naïve patients.

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 including humans 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 salt 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 stroke rehabilitation including Constraint Induced Movement Therapy.

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.

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