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Algernon Pharmaceuticals Screens First Subject in Phase 1 DMT Human Stroke Study

VANCOUVER, British Columbia, Nov. 16, 2022 (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 commenced screening subjects for its Phase 1 clinical study of an intravenous formulation of AP-188 ("N,N-Dimethyltryptamine" or "DMT") in the Netherlands. The trial will be conducted at the Centre for Human Drug Research ("CHDR") in Leiden. DMT is a known psychedelic compound that is part of the tryptamine family. The company plans to open enrollment shortly and dose the first subject of the study in December 2022.

The purpose of the study is to identify the safety, tolerability, and pharmacokinetics of DMT when administered as an intravenous bolus followed by prolonged infusion, for durations which have never been studied clinically. In addition, several pharmacodynamic measures believed to be associated with neuroplasticity, including both measurements of biochemical markers and electroencephalographic readings, will be recorded.

The first part of the study will use a single-escalating dose design, aimed at identifying a safe and tolerable dose that will not produce psychedelic effects, while the second part will test the effects of repeated administrations of this 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.

Since there have already been several Phase 1 studies successfully conducted on DMT, the Company is not anticipating any serious adverse events or safety issues arising from its study. The resulting data generated will help the Company to plan both its Phase 2 acute stroke and rehabilitation studies more effectively.

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, at a sub-psychedelic dose, helps promote structural and functional neuropasticity. 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.

"We are very excited to be initiating our DMT clinical stroke research program with our Phase 1 study at CHDR in the Netherlands," said Christopher J. Moreau CEO of Algernon Pharmaceuticals. "The preclinical data shows that DMT promotes the production of brain-derived neurotrophic factor which is an important part of the brain's recovery process after an injury like a stroke."

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 Amazon basin. DMT can also be synthesised in a laboratory.

Algernon has filed patents for DMT pamoate and nicotinate (novel 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 Canadian clinical stage drug development company investigating multiple drugs with global unmet medical needs. Algernon has active research programs for IPF with chronic cough, chronic kidney disease, and a psychedelic program investigating a proprietary form of DMT for stroke.

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Source: Algernon Pharmaceuticals