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Algernon NeuroScience Provides Update on Phase 1 DMT Clinical Study, Drug Found Safe to Proceed to Next Phase

VANCOUVER, British Columbia, Feb. 16, 2023 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (the "Company" or "AGN Pharma") (CSE: AGN) (FRANKFURT: AGW0) (OTCQB: AGNPF), a Canadian clinical stage pharmaceutical development company, is pleased to advise that its subsidiary Algernon NeuroScience (AGN Neuro), has completed dosing of the first cohort in its Phase 1 clinical study of an intravenous formulation of AP-188 ("N,N-Dimethyltryptamine" or "DMT"), a known psychedelic compound that is part of the tryptamine family. AGN Neuro also reports that the safety review committee has approved moving the study forward with the next cohort at an escalated dose after observing no safety or tolerability issues.

The trial is being conducted at the Centre for Human Drug Research ("CHDR") in Leiden, Netherlands. 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 6 hours, a duration that has never before 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.

Once the correct dose has been established in the first part of the study, the second part of the study will include dosing subjects for 6 hours, with repeated dosing over a two-week period. There will be up to 60 healthy volunteers enrolled in total, which will include both psychedelic experienced and psychedelic naïve subjects.

The Company has been working with its DMT and stroke experts from its medical advisory board to help design the planned Phase 2 studies of a sub-psychedelic dose of DMT in acute stroke and rehabilitation. The studies are expected to dose patients immediately following confirmation of their ischemic stroke diagnosis by imaging and will test the effects of DMT versus placebo on both the progress of the infarct and also on patients' recovery following the stroke.

"We are very pleased by the progress made by CHDR, as well as with the safety profile of DMT observed at this stage in our Phase 1 study," said Christopher J. Moreau CEO of Algernon Pharmaceuticals. "Although DMT has been previously investigated in humans, we are breaking new ground in this study in terms of both the length of the infusion and the frequency of exposure."

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 NeuroScience

Algernon NeuroScience is a private equity subsidiary of Algernon Pharmaceuticals and has been created to advance the Company's DMT stroke research program. AGN Neuro has filed a Form 1-A offering statement with the U.S. Securities and Exchange Commission, seeking qualification to raise up to USD \$10M for AGN Neuro by offering up to 37.5% of its common shares, (including the maximum amount of bonus shares) with majority ownership residing with AGN Pharma, under a Tier II Regulation A+ offering.

About Algernon Pharmaceuticals Inc.

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.

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: Algeron Pharmaceuticals