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Algernon NeuroScience and the Centre for Human Drug Research to Present DMT Phase 1 Stroke Clinical Data at the Interdisciplinary Conference on Psychedelic Research June 6 – 8th, 2024

VANCOUVER, British Columbia, April 24, 2024 (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 announce that its subsidiary Algernon NeuroScience (AGN Neuro), along with the Centre for Human Drug Research (CHDR), will present its Phase 1 stroke study data at the Interdisciplinary Conference on Psychedelic Research being held June 6-8, 2024 in Haarlem, the Netherlands. AGN Neuro is the world's first company to investigate DMT for the treatment of stroke and its ability to promote neuroplasticity in the healing of brain injuries.

Dr. Katelijne Van der Heijden, research physician at the CHDR and study co-investigator for the DMT Phase 1 clinical trial, will present "Safety, pharmacokinetics and pharmacodynamics of *N*,*N*-Dimethyltryptamine (DMT) administered intravenously over 6 hours in healthy volunteers."

The single escalating dose Phase 1 DMT stroke trial was conducted at the CHDR in Leiden, Netherlands. The purpose of the study was to identify the safety, tolerability, and pharmacokinetics of sub-psychedelic doses of DMT when administered as an intravenous bolus followed by a prolonged infusion of 6 hours, a period which has never been studied clinically. In addition, several pharmacodynamic measures believed to be associated with neuroplasticity, including both measurements of biochemical markers and electroencephalographic readings, were recorded.

AGN Neuro reported that the safety review committee confirmed that there were no safety or tolerability issues with the highest dose, which was able to maintain plasma DMT concentrations at targeted levels and which was below the established psychedelic dose.

The psychedelic dose of DMT was previously identified as 0.2 mg/kg by Dr. Rick Strassman, DMT researcher and author of the book *DMT: The Spirit Molecule* (2001*)* and AGN Neuro consultant*,* in his ground-breaking DMT human studies in the early 1990s. AGN Neuro is the first company to test DMT at single escalating concentrations with an IV dose for a 6-hour duration.

Based on the positive data from the Phase 1 DMT stroke clinical trial, the Company plans to begin a Phase 2a clinical trial in acute ischemic stroke patients in 2024.

About DMT

The decision to investigate DMT for stroke treatment was based on the ground-breaking 2020-published rat occlusion stroke study by Nardai et al showing that DMT reduced infarct volume and led to an almost full recovery of motor function 30 days after a single treatment of DMT, with statistical significance.[1]

This was also one of numerous pre-clinical studies that showed DMT increases brain derived neurotrophic factor (BDNF), the main neurotrophin involved in healing the brain after an injury. DMT activates pathways involved in forming neuronal connections and has been shown to increase the capacity of neurons to form new neural connections by expanding cell morphology and the growth of dendritic spines; the sites of signal transduction between neurons.

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.

DMT is an agonist of multiple receptors, including serotonin receptors and the sigma-1 receptor. Sigma-1 is a multi-faceted stress-responsive receptor which promotes cell survival, neuroprotection, neuroplasticity, and neuroimmunomodulation. Further, DMT promotes the release of Brain-Derived Neurotrophic Factor (BDNF), a protein which can aid in recovery after a brain injury.

DMT has a rapid onset, intense psychedelic effects, and a relatively short duration of action at high doses. At sub-hallucinogenic doses, DMT has been shown to induce and improve structural and functional neuroplasticity both *in vitro* and in preclinical murine models.

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 and TBI. The Company has also filed claims for combination therapy of DMT and stroke rehabilitation including Constraint Induced Movement Therapy.

Phase 2a Stroke Study Design

Subjects with a confirmed diagnosis of ischemic stroke will be randomized in blinded fashion to receive either DMT or placebo. The primary outcome measure of the study will be safety, and information will be gained on measures of efficacy including preservation of brain tissue, motor recovery, depression and numerous biomarkers linked to the pathophysiology of stroke.

The decision to advance into a Phase 2 study was based on positive data from the Company's Phase 1 trial conducted at the Centre for Human Drug Research (CHDR) in Leiden, Netherlands. This study showed that plasma levels of DMT associated with neuroplasticity in preclinical studies could be achieved with a prolonged, 6-hour infusion of AP-188 at a dose which did not cause a psychedelic experience. The amount given exceeded the human equivalent of the dose used in preclinical studies in rats which demonstrated neuroprotective effects.

About Algernon NeuroScience

Algernon NeuroScience is a 100% owned private equity subsidiary of Algernon Pharmaceuticals and has been created to advance the Company's DMT stroke and traumatic brain injury (TBI) research program. For more information visit www.algernonneuroscience.com.

About Algernon Pharmaceuticals Inc.

Algernon Pharmaceuticals is a Canadian clinical stage drug development company investigating multiple drugs for unmet global medical needs. Algernon Pharmaceuticals is the parent company of a private subsidiary called Algernon NeuroScience, that is advancing a psychedelic program investigating a proprietary form of DMT for stroke and traumatic brain injury and has an active research program for chronic kidney disease.

Algernon recently announced that it closed on its agreement with Seyltx Inc., a privately owned U.S. based drug development company, for the acquisition of Algernon's NP-120 (Ifenprodil) research program for the purchase price of USD $2M cash and a 20% common share equity position in Seyltx. For more information visit https://www.algernonpharmaceuticals.com

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