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Algernon NeuroScience Announces 40 Patient Phase 2 Psychedelic Drug DMT Stroke Study

VANCOUVER, British Columbia, Aug. 08, 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 announce that its subsidiary Algernon NeuroScience (AGN Neuro), has completed a feasibility study and has finalized its clinical trial design for a 40 patient Phase 2 DMT Stroke study. 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.

The Phase 2 human stroke trial will study an intravenous sub-psychedelic dose of DMT in patients who are hospitalized after having suffered an acute ischemic stroke.

Algernon consultant Dr. Rick Strassman, DMT research pioneer and author of the books *DMT: The Spirit Molecule* and *The Psychedelic Handbook* commented: "I am encouraged by the results of Algernon's Phase 1 study in which a prolonged infusion of DMT achieved the desired pharmacokinetics. In addition, psychological and physiological responses remain below those associated with psychedelic effects. These data support moving into clinical studies in stroke patients, and I will closely follow the Phase 2 study as it advances."

The decision to investigate DMT for stroke treatment was based on the ground-breaking 2020-published rat occlusion stroke study showing that DMT reduced infarct volume and led to an almost full recovery of motor function 30 days after a single treatment with statistical significance.This was also one of numerous pre-clinical studies that showed DMT increases brain derived neurotropic 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. DMT has also been shown to protect at risk tissue from death, a process AGN Neuro plans to capitalize on by providing the drug in the acute period before damage has a chance to substantially expand.

"DMT's ability to promote neuroplasticity, already demonstrated preclinically, combined with its neuroprotective effects make it unique amongst potential therapies being investigated for stroke," said Dr. David Nutt, Edmund J. Safra Professor of neuropsychopharmacology at Imperial College London, and Algernon consultant. "The potential benefits of DMT in stroke patients not only at the time of their injury, but also in the post-stroke recovery period, makes Algernon's upcoming trial very, very exciting."

AGN Neuro is planning to conduct the study at multiple locations in Europe using the

Company's existing finished product supply of intravenous DMT. Ethics submission is planned for later in Q3 with the study starting a short time after approval.

Phase 2 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.

"Our planned Phase 2 stroke study investigating DMT, the first of its kind in the world, is very exciting and we look forward to getting the trial underway as soon as possible," said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. "We are investigating DMT as a potential new therapeutic treatment that could have a positive impact on ischemic stroke patients worldwide."

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.

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 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.

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 and repurposing company investigating multiple drugs for unmet global medical needs. Algernon Pharmaceuticals has active research programs for chronic cough and chronic kidney disease and is the parent company of a private subsidiary called Algernon NeuroScience, that is advancing a psychedelic program investigating a proprietary form of psychedelic DMT for stroke and TBI. For more information visit www.algernonpharmaceuticals.com.

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: Algernon Pharmaceuticals