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ALGERNON HEALTH™

Algernon NeuroScience Doses First Subject in Phase 1 DMT Clinical Stroke Study

VANCOUVER, British Columbia, Jan. 17, 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 dosed the first subject in its Phase 1 clinical study of an intravenous formulation of AP-188 (“N,N-Dimethyltryptamine” or “DMT”) in the Netherlands. The trial is being conducted at the Centre for Human Drug Research in Leiden. DMT is a known psychedelic compound that is part of the tryptamine family.

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 stroke recovery.

“I am delighted that Algernon NeuroScience has begun their Phase 1 DMT study,” said Dr. Rick Strassman, author of DMT: The Spirit Molecule and Algernon consultant. "Based on what we know about DMT, I believe a prolonged infusion of a sub- psychedelic dose of this compound will be safe and may activate multiple neuroregenerative pathways, including elevations of BDNF. Such effects may prove beneficial in ischemic stroke patients acutely and in their rehabilitation.”

Algernon consultant Dr. David Nutt, who is the Edmund J. Safra Professor of Neuropsychopharmacology in the Division of Brain Science, Department of Medicine, Hammersmith Hospital, Imperial College London stated, “A significant number of promising stroke drugs have failed because they were focussed on trying to be neuroprotective of the brain during a stroke.” He continued, “It appears from the pre-clinical data that DMT is promoting neuroplasticity, a key mechanism in recovery once the stroke has occurred, which is a new and exciting approach to stroke treatment.”

The purpose of the Phase 1 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 same 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 the study. The resulting data generated will help the Company to plan both a Phase 2 acute stroke and rehabilitation study more effectively.

The Company has been working with its DMT and stroke experts from its medical advisory board to help design the planned Phase 2 studies in acute stroke and rehabilitation. The planned 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.

"This Phase 1 study is an important milestone as we advance our investigation of DMT for the treatment of stroke," said Christopher J. Moreau CEO of Algernon Pharmaceuticals. "We anticipate receiving data from this study in Q3 2023, and potentially beginning Phase 2 studies in stroke patients by the end of the calendar year."

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. 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.

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Source: Algernon Pharmaceuticals