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Algernon NeuroScience Announces Successful Completion of Highest Planned Single Dose in DMT Phase 1 Trial; Accelerates Plans for Phase 2 Stroke and TBI Studies

VANCOUVER, British Columbia, June 05, 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 successfully completed dosing of the third and planned final cohort in its escalating dose Phase 1 clinical study of an intravenous (IV) formulation of AP-188 ("N,N-Dimethyltryptamine" or "DMT"). AGN Neuro is the world's first company to investigate DMT for both the treatment of stroke and traumatic brain injury (TBI).

AGN Neuro also reports that the safety review committee has 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.

In pre-clinical studies, DMT increases brain derived neurotrophic factor (BDNF) which is believed to be a key mechanism involved in healing the brain after an injury. DMT is believed to activate pathways involved in forming neuronal connections and has been shown to increase the number of dendritic spines on cortical neurons. Dendritic spines form synapses (connections) with other neurons and are a critical site of molecular activity in the brain.

The single escalating dose Phase 1 trial was conducted at the Centre for Human Drug Research 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 plans to publish the data from the study in an upcoming issue of a peer reviewed, scientific publication.

Based on the success of the highest tested dose, the second part of the study, which will be scheduled to begin at a later time, will include dosing subjects for 6 hours with repeated

administrations over a two-week period. AGN Neuro has now established a single dose regimen which can now be used in its first Phase 2 study for stroke and TBI.

“Neuroplasticity’s role in healing the brain after an injury is one of the most exciting areas of research going on globally in the pursuit of a treatment for stroke and TBI, and AGN Neuro is at the forefront of this work,” said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. “Now that we have established the safety of a single sub psychedelic dose of DMT, we are planning to accelerate our DMT Phase 2 studies accordingly, for both stroke and TBI.”

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 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.

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 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 and TBI. For more information visit www.algernonpharmaceuticals.com.

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Source: Algernon Pharmaceuticals