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Algernon Pharmaceuticals Receives Positive Feedback from U.S. FDA for Psychedelic Drug DMT Clinical Research Program for Stroke

VANCOUVER, British Columbia, May 17, 2021 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) (the "Company" or "Algernon") announces it has received positive feedback from the U.S. Food and Drug Administration (FDA) regarding its plans to investigate AP-188 ("N,N-Dimethyltryptamine" or "DMT"), a known psychedelic compound that is part of the tryptamine family, as an adjunct to physical therapy in the rehabilitation of stroke.

In a Pre-IND request submitted March 16, 2021, Algernon sought direction from the FDA regarding the design and scope of the Company's preclinical and early phase stroke clinical programs. The FDA is in agreement with the Company's planned preclinical efficacy experiments and offered guidance with regards to supportive preclinical safety studies. In addition, the FDA provided valuable input into the design of the Company's planned Phase 1 clinical trial, which will be conducted through Hammersmith Medicines Research in the UK, in Q4 2021.

"On February 1, 2021, Algernon announced that it was planning to be the first Company in the world to test DMT in human clinical trials for stroke, and that is an objective we are aggressively pursuing," said Christopher J. Moreau CEO of Algernon Pharmaceuticals. "While we will begin with investigating DMT as an adjunct to physical therapy in the rehabilitation of stroke patients, we are currently engaged in preclinical research that will inform us on our planned Phase 2 for ischemic stroke as well. Algernon will file an additional Pre-IND meeting request with the FDA for its planned ischemic stroke program when its preclinical research program is complete."

Algernon has filed new provisional patents for new 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 Constraint Induced Movement Therapy.

About Algernon Pharmaceuticals Inc.

Algernon is a drug re-purposing company that investigates well-tolerated, already approved drugs, including naturally occurring compounds for new disease applications, moving them efficiently and safely into new human trials, developing new formulations and seeking new regulatory approvals in global markets. Algernon specifically investigates compounds that have never been approved in the U.S. or Europe to avoid off label prescription writing.

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