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Algernon Pharmaceuticals Awards DMT Manufacturing Contract to Dalton Pharma for Stroke Program

VANCOUVER, British Columbia, Feb. 19, 2021 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) (the "Company" or "Algernon"), a clinical stage pharmaceutical development company, announces that it has awarded the contract to manufacture the active pharmaceutical ingredient and finished product for its formulation of AP-188 ("N,N-Dimethyltryptamine or DMT"), to Canadian-based Dalton Pharma Services ("Dalton").

Dalton is a Health Canada approved, and FDA inspected, GMP contract provider of integrated chemistry, drug development and manufacturing services to the pharmaceutical and biotechnology industries. Dalton is a class 4 controlled substance licensed manufacturer with Health Canada and has extensive experience in synthesizing psilocybin and tryptamine derivatives.

As work has now begun on the synthesis of DMT, the Company will be filing its pre-IND (Investigational New Drug) meeting request with the U.S. FDA shortly, and has already started work on the planning of its Phase 1 and Phase 2 clinical studies.

"We are very pleased to have appointed Dalton Pharma Services to synthesize our GMP DMT supply," said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. "Based on positive pre-clinical data, the Company believes that DMT may help treat patients who have suffered from a stroke, which is one of the most devastating injuries a human being can experience."

DMT Background

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 and has been used in religious ceremonies as a traditional spiritual medicine by indigenous people in the Amazonian basin. DMT can also be synthesised in a laboratory.

At higher doses, DMT has a rapid onset, intense psychedelic effects, and a relatively short duration of action with an estimated half-life of less than fifteen minutes. Like other hallucinogens in the tryptamine family, DMT binds to serotonin receptors to produce euphoria and psychedelic effects. Because the effects of DMT do not last very long, it has been referred to in some circles as the "businessman's trip".

Named the "Spirit Molecule" by Dr. Rick Strassman, an American clinical associate professor of psychiatry and DMT research pioneer, DMT has been shown to induce neuroplasticity in a number of key preclinical studies. DMT is believed to activate pathways involved with

forming neuron connections and has been shown in studies to increase the number of dendritic spines on cortical neurons. Dendritic spines form synapses (connections) with other neurons and are a major site of molecular activity in the brain.

While Dr. Strassman's Phase 1 bolus intravenous human study identified the sub-hallucinogenic dose of DMT in humans, another preclinical animal study demonstrated this same dose level still retains the neuroplastic effect seen in higher hallucinogenic doses.

Algernon will be investigating an intravenous sub-hallucinogenic dose of DMT in its research and clinical studies.

DMT – Building the Case for Stroke

Data from a study published in *Experimental Neurology*, in May 2020 showed that in a rat model of cerebral ischemia-reperfusion injury, DMT reduced the infarct (dead cells) volume and improved functional recovery.

Key Findings:

- Animals treated with DMT displayed lower lesion volumes than control animals measured by MRI 24 hours following the occlusion. ($p = 0.0373$)
- Animals in the DMT group improved motor function more quickly and to a greater extent than the control group; The differences became significant on the 4th day ($p = 0.0325$) and persisted throughout a 30-day follow-up.
- mRNA expression of brain-derived neurotrophic factor (BDNF) was upregulated in both the peri-infarct cortex ($p = 0.0273$) and contralateral cortex ($p = 0.0048$) as well as in serum ($p < 0.0001$). BDNF is a key facilitator of neuroplasticity.

The full study can be viewed at the following link:

<https://www.sciencedirect.com/science/article/abs/pii/S0014488620300765?via%3Dihub>

About Dalton Pharma Services

Dalton Pharma Services is a leading cGMP contract service provider of integrated drug discovery, development and manufacturing services to the pharmaceutical and biotechnology industries. We are FDA Inspected and Health Canada approved, and bring over 30 years of experience to every project, delivering fully integrated solutions with an emphasis on speed, flexibility and quality. <https://www.dalton.com/>

About Algernon Pharmaceuticals Inc.

Algernon is a drug re-purposing company that investigates safe, 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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Source: Algernon Pharmaceuticals