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ALGERNON HEALTH™

Algernon NeuroScience Initiates Traumatic Brain Injury Research Program With DMT; Appoints Global TBI Expert as Advisor

VANCOUVER, British Columbia, Feb. 21, 2023 (GLOBE NEWSWIRE) -- Algernon Pharmaceuticals Inc. (CSE: AGN) (FRANKFURT: AGW) (OTCQB: AGNPF) (the "Company" or "Algernon"), a clinical stage pharmaceutical development company, is pleased to announce that its subsidiary Algernon NeuroScience (AGN Neuro) has added a new clinical research program for the treatment of Traumatic Brain Injury (TBI) with AP-188 ("N,N-Dimethyltryptamine or DMT"). AGN Neuro plans to be the first company globally to investigate DMT for TBI in humans and is planning to begin a Phase 2 clinical trial in Q4, 2023.

AGN Neuro has an active stroke research program underway and is currently conducting a Phase 1 DMT study in the Netherlands at the Centre for Human Drug Research. It recently announced that it had completed dosing subjects in the first cohort of the study and that the safety review committee has approved moving the study forward with the next cohort at an escalated dose after observing no safety or tolerability issues. AGN Neuro's clinical plan is to use the data from the Phase 1 Study of DMT currently underway, to accelerate directly into a Phase 2 TBI study in the fall of 2023. AGN Neuro, in consultation with its TBI advisors, may plan and conduct certain preclinical research to help better guide the planned Phase 2 clinical study.

AGN Neuro's decision to investigate DMT for TBI is based on several factors, specifically:

- There are many commonalities between stroke and TBI where DMT has demonstrated benefit in several preclinical studies, including: neuroinflammation, mitochondrial dysfunction, reactive oxygen species, excitotoxicity, and spreading depolarizations.

- DMT is an agonist of sigma-1, a part of the body's natural defense against physiological stresses, which is elevated following TBI. DMT increases brain derived neurotropic factor (BDNF), a protein which plays a key role in neuroplasticity. Natural levels of BDNF in the brain are decreased following TBI; however, expression of TrkB mRNA, the receptor to which BDNF binds, is increased as the brain seeks to compensate for the injury. Studies have shown that exercise-induced increases in BDNF generally improve recovery following TBI, and that blocking the effects of BDNF attenuate the improvement. Furthermore, increased levels of BDNF following TBI are correlated with improved cognitive function.

- On-going symptoms of TBI are often psychological and cognitive; a number of psychedelic drugs, including DMT, have already shown therapeutic potential in clinical trials in some of these conditions.

- In TBI, classified as mild according to the Glasgow coma scale, up to 50% of TBI patients have symptoms that have not resolved after 6 months. Millions of mild TBIs occur each year, and that number is expanding with increased access to motor vehicles in the developing world and the associated increase in accidents. There are currently no drugs approved for treatment of TBI of any severity.

AGN Neuro is also pleased to announce that it has appointed global TBI expert Dr. Andrew Maas as a scientific and medical advisor to help guide its TBI research program. “There is a great need to improve the recovery potential in patients after TBI, and the role of neuroplasticity is a promising target, for which DMT holds potential,” stated Dr. Maas.

About Dr. Andrew Maas, MD, PhD

Dr. Andrew I. R. Maas is Emeritus Professor of Neurosurgery at the Antwerp University Hospital and University of Antwerp. He holds positions as past Chairman of the Neurotraumatology Committee of the World Federation of Neurosurgical Societies (WFNS) and the International Neurotrauma Society, and is Co-Chairman of the European Brain Injury Consortium. He has a vast experience as a general neurosurgeon and has specific research interests in Traumatic Brain Injury and neuro-intensive care.

Dr. Maas was the Principal Investigator of the IMPACT study group (International Mission on Prognosis and Clinical Trial design in TBI), that was awarded an NIH grant (2003-2011) and resulted in over 55 publications and recommendations for improved trial design. Currently, together with Prof David Menon, University of Cambridge, he coordinates the large-scale collaborative project CENTER-TBI: Collaborative European NeuroTrauma Effectiveness Research in TBI (www.center-tbi.eu), supported by the FP7 program of the European Union (Grant no: 602150; duration:2013-2020). He received an Honorary doctoral degree at the Burdenko Institute of Neurosurgery in Moscow in 2013 and Lifetime Achievement Award for his work on traumatic brain injury from the International Brain Injury Association in 2016.

Dr. Maas is member of various editorial boards, review committees and is a reviewer for over 35 international journals. In total he has authored over 250 publications in peer reviewed international journals.

“We welcome Dr. Maas as our first TBI program advisor,” said Christopher J. Moreau, CEO of Algernon. “After discussing key elements of the TBI program during our planning stages, Dr. Maas, along with multiple other global TBI experts, voiced their support for AGN Neuro moving forward to investigate DMT as a potential new TBI therapy.”

AGN Neuro is also pleased to announce that it has appointed global TBI expert Dr. Andrew Maas as a scientific and medical advisor to help guide its TBI research program. The Company has also filed claims for combination therapy of DMT and Constraint Induced Movement Therapy (“CIMT”).

About TBI

According to the National Institute of Neurological Disorders and Stroke, a TBI can be caused by a forceful bump, blow, or jolt to the head or body, or from an object that pierces the skull and enters the brain. Not all blows or jolts to the head result in a TBI.

Some types of TBI can cause temporary or short-term problems with normal brain function, including problems with how the person thinks, understands, moves, communicates, and acts. More serious TBI can lead to severe and permanent disability, and even death.

Some injuries are considered primary, meaning the damage is immediate. Other outcomes of TBI can be secondary, meaning they can occur gradually over the course of hours, days, or appear weeks later. These secondary brain injuries are the result of reactive processes that occur after the initial head trauma.

There are two broad types of head injuries: Penetrating and non-penetrating:

1. Penetrating TBI (also known as open TBI) happens when an object pierces the skull (e.g., a bullet, shrapnel, bone fragment, or by a weapon such as hammer or knife) and enters the brain tissue. Penetrating TBI typically damages only part of the brain.
2. Non-penetrating TBI (also known as closed head injury or blunt TBI) is caused by an external force strong enough to move the brain within the skull. Causes include falls, motor vehicle crashes, sports injuries, blast injury, or being struck by an object.

Some accidents such as explosions, natural disasters, or other extreme events can cause both penetrating and non- penetrating TBI in the same person.

Global TBI Treatment Market:

The global TBI market is projected to grow from USD $3.1 billion in 2021 to USD $4.5 billion by 2026 at CAGR of 8.0%, according to a study by Global Market Estimates.

The increasing prevalence of TBI's, rising preference for minimally invasive procedures, and increasing awareness regarding early diagnosis of brain injuries are the major factors expected to fuel the market growth. In addition, the adoption of advanced medical devices and products and the increasing implementation of government policies for healthcare services are additional factors contributing to the market growth.

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 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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