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ADvantage Therapeutics Developing Therapies to Treat Neurodegenerative Conditions with Focus on Alzheimer's Disease

Company Awaits Regulatory Clearance to Conduct Confirmatory Phase 2b Trial for Lead Product Candidate AD04™ to Establish Safety and Efficacy

MIAMI, March 15, 2023 (GLOBE NEWSWIRE) -- ADvantage Therapeutics, Inc. ("ADvantage" or "the Company"), which is developing therapies to treat neurodegenerative conditions with a central focus on Alzheimer's disease, today announces it is working on the development of its lead candidate, the AD04™ compound for the treatment of early Alzheimer's disease (AD).

Most recently, a 2mg dose of AD04™ served as a control arm in a prior study of another compound, where it demonstrated a statistically significantly slower decline in outcomes (cognition and Quality of Life) than other arms of that trial. In addition, the AD04™ control group showed slower decline in MRI-measured hippocampal volume as a biomarker of AD progression. To date, preclinical studies have shown that AD04™ decreased the number of inflammatory microglial cells in the hippocampus of mouse models. The increase of inflammatory microglial cells in the hippocampus are commonly associated with the eventual development of amyloid-lipid plaques in the brain.

The Company has applied for clinical trial authorization (CTA) in six European countries to conduct a Phase 2b confirmatory trial designed to verify and enhance the current understanding of the product in the context of treating early Alzheimer's disease. The Phase 2b study will be a randomized, placebo-controlled, double-blind study designed to confirm proof-of-concept and establish safety and efficacy of AD04™ (injectable alhydrogel) in early AD patients. The 12-month study will measure hippocampal volume as a primary objective/biomarker endpoint. Other measured outcomes include the Neuropsychiatric Inventory (NPI), the Alzheimer's disease Assessment scale – cognition 13-item scale (ADAScog13), the Alzheimer's Disease Cooperative Study – Activities of Daily Living Standards (ADCS-ADL), and the patient Quality of Life-Alzheimer's disease.

ADvantage Therapeutics CEO Jeffrey Madden stated, "Alzheimer's disease is devastating to patients, their caregivers and loved ones. To date, there is no disease-modifying drug approved on a global scale that addresses this important unmet medical need which affects 44 million patients worldwide. We are dedicated to developing AD04™, which shows promise in approaching the disease from an immunological perspective by activating mechanisms in the brain and peripheral immune system to reduce inflammatory processes in the brain. AD04™ is a novel immunotherapy for Alzheimer's which if validated and approved has the potential to democratize Alzheimer's treatment. Relative to monoclonal antibodies, AD04™ has a low manufacturing cost, simple storage, and can be easily administered subcutaneously. Most importantly, safety and efficacy that if clinically proven has the potential to provide affordable access to a better life."

"We eagerly await approval to launch this confirmatory trial, which may provide a new approach to the treatment of Alzheimer's disease. After observing the potential for AD04™ in a prior study, we have designed our confirmatory study to provide additional evidence of our clinical endpoints. We look forward to reporting our first CTA approval soon and embarking on this important clinical study which informs our Mission as a Company," Mr. Madden concluded.

About AD04™

ADvantage Therapeutics is developing AD04™ as a novel immunotherapy for early Alzheimer's disease. The compound has been used as an adjuvant in human and animal vaccination programs. In a previous trial, AD04™ serving as a control arm against another compound appeared to demonstrate statistically significantly slower decline over other treatment groups in cognitive and quality life clinical measures. AD04™ also showed slower decline in hippocampal volume as a biomarker.

The Company believes that rather than being limited to a specific aspect of AD pathology, such as amyloid beta or tau, the use of AD04™ may address the immunological mechanisms in the brain and peripheral nervous system. The Company believes AD04™ may act as an immunomodulator, stimulating and/or regulating the immune system to reduce AD pathology.

About Alzheimer's disease

About 44 million people worldwide suffer from Alzheimer's disease, and it is the sixth leading cause of death in industrialized countries. According to the World Health Organization, total worldwide cost of dementia was estimated to be \$1.3 trillion in 2019. While the FDA provisionally approved an anti-amyloid beta antibody, aducanumab, in 2021, widespread coverage has not been granted, nor have European countries approved the product. The socio-economic burden of Alzheimer's disease is enormous. AD devastates patients' lives and that of their families. They lose their memories and independence, and the loss of a loved relation leaves behind guilt, grief, and anger. Alzheimer's disease is a high unmet medical need as there is currently no disease-modifying drugs approved worldwide. The availability of a safe, effective, affordable drug would transform the life of an AD patient from accepting a debilitating disease to the retention of their personality, independence, and dignity.

About ADvantage Therapeutics

Headquartered in Miami, ADvantage Therapeutics is developing therapies to treat neurodegenerative conditions with a central focus on Alzheimer's disease. The Company's lead compound AD04™ is an injectable therapy in the process of entering into a confirmatory Phase 2b clinical trials in Europe to evaluate safety and efficacy of the product in early Alzheimer's disease. The Company believes that Alhydrogel may act as an immunomodulator, stimulating and regulating the immune system to reduce AD pathology, rather than limiting therapy to the aggregation of the proteins present once pathology is present. The Company is also exploring additional approaches to mitigating neurodegenerative disease, which it believes will eventually have an overall impact on longevity.

Safe Harbor-Forward-Looking Statements

This press release may contain forward-looking statements, including statements of potential mode of action, potential clinical effect, potential safety, and Advantage's potential clinical development program and pipeline program. ADvantage is in the early stages of developing and testing its AD04™ compound and may not receive regulatory approval to conduct the contemplated Phase 2b trial. The described clinical effect of our lead compound AD04™ is primarily based on results of a Phase 2 study designed to test a different compound. The described results need to be reproduced for proof of concept, might not be representative of larger scale clinical trials, and do not guarantee future regulatory approval or clinical success. Any preclinical results presented here are interim. The mechanism of action of AD04™ as potentially determined in our future investigations, particularly in future clinical trials with patients with Alzheimer's disease, might differ compared to the one presented.

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