

## **ADvantage Therapeutics Has Commenced Enrollment for Its Phase 2b Clinical Trial of AD04™ for Treatment of Alzheimer’s Disease**

MIAMI, November 27, 2023 (GLOBE NEWSWIRE) – ADvantage Therapeutics, Inc. (“ADvantage” or “the Company”), a pioneer in developing therapies for neurodegenerative conditions by addressing the biology of aging, today announced the first patient enrolled in the Company’s European Phase 2b clinical trial on its lead candidate, AD04™ for the treatment of mild Alzheimer’s disease (AD).

The Phase 2b randomized, double-blind, placebo-controlled trial aims to confirm proof-of-concept and establish the safety and efficacy of AD04™ in patients with mild AD. The first patient was enrolled at Institut Neuromed, Korneuburg, Austria. The study is authorized to be conducted in Austria, France, Poland, Bulgaria, and Slovakia, and is expected to expand to Germany and the U.K. in the coming months.

Dr. Andreas Winkler, MSc., principal investigator at Institut Neuromed, commented, “AD represents a significant global problem as the adult population is aging which further challenges our ability to care for those who suffer from this terrible, progressive disease. AD04 represents a significant departure from approaches seen to date and one that may change our understanding of how to manage it as well as the disease itself. We look forward to continuing to participate in the trial to help contribute to its development.”

The primary endpoint of the 12-month study is to be a composite score integrating ADAScog, ADCS-ADL and CDR-sb (at 12 months). Other measured outcomes include hippocampal volume, CDR-sb, 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.

In a previous study, a 2mg dose of AD04™ used in a control arm exhibited a statistically significantly slower decline in cognitive and quality of life measures compared to other arms of that trial. The AD04™ control group also showed slower decline in MRI-measured hippocampal volume as a biomarker of AD progression. Preclinical studies have indicated that AD04 decreased the number of pro-inflammatory microglial cells in the hippocampus of mouse models. Pro-inflammatory microglia are one of the neuropathological events observed in the brains of Alzheimer’s patients.

Achim Schneeberger, M.D., chief medical officer of ADvantage, further commented, “Inclusion of this first patient is representative of many years and many dedicated professionals collaborating toward the common goal of better treating Alzheimer’s disease. We look forward to continuing our collaboration with the European regulatory agencies and the clinical sites to populate this important trial.”

Recently, the Company received an [Innovation Passport for the treatment of AD under the Innovative Licensing and Access Pathway \(ILAP\)](#) for AD04™ in the United Kingdom. This allows for close collaboration with the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC) and NHS England and NHS Improvement (NHSE&I). In addition, patients are considered key partners, and the patient voice is integrated at every

development stage. ILAP incorporates the concepts of innovation and patient need according to the MHRA.

“It is gratifying to achieve this milestone after months of labor by a most dedicated team of professionals. We intend to create medicines that will help to prolong lives but also improve their quality. We look forward to providing additional updates on the progress of this potentially landmark trial,” added Jeffrey Madden, ADvantage Therapeutics CEO.

ADvantage Therapeutics is dedicated to advancing the science of neurodegenerative diseases and committed to developing innovative therapies that can make a meaningful difference in the lives of patients. For more information on ADvantage Therapeutics, Inc., please visit [www.advantagetherapeutics.com](http://www.advantagetherapeutics.com).

### **About AD04™**

ADvantage Therapeutics is developing AD04™ as a novel therapy for mild 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 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, AD04™ may address innate immunological mechanisms in the brain. The Company believes AD04™ may function as an immunomodulator, stimulating and/or regulating the innate immune system to reduce AD pathology.

### **About Alzheimer’s Disease**

About forty-four million people worldwide suffer from Alzheimer’s Disease, and it is the sixth leading cause of death in industrialized countries. According to Alzheimer’s Disease International, the annual global cost of dementia is now above US\$ 1.3 trillion and is expected to rise to US\$ 2.8 trillion by 2030. The socio-economic burden of Alzheimer’s Disease is enormous. AD devastates the lives of patients and 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 are 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 personality, independence, and dignity.

### **About ADvantage Therapeutics**

Headquartered in the Wynwood neighborhood 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 mild Alzheimer’s Disease. The Company believes that AD04™ may function as an immunomodulator, stimulating and regulating the immune system to reduce AD pathology, rather than limiting therapy to AD-modified proteins such as amyloid and tau. The Company is also exploring additional approaches to mitigating neurodegenerative disease, which it believes will eventually have an overall impact on longevity.

### **About ADvantage Therapeutics GmbH**

ADvantage Therapeutics GmbH, founded in 2021, is the Vienna BioCenter-based subsidiary of ADvantage Therapeutics, Inc., where the Company conducts early research and drug development. ADvantage is developing therapies to treat neurodegenerative conditions like Alzheimer's Disease (AD).

### **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 evaluate a different compound. The described results need to be confirmed 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 from the one presented.

### **Contacts:**

For ADvantage Therapeutics  
195 NW 40th Street  
Miami, FL 33127

Jeffrey Madden CEO  
jeff@advantagetherapeutics.com  
(786) 542-5499

David Buchsbaum CFO  
david@advantagetherapeutics.com  
(786) 542-5499

### *For Media:*

Jules Abraham  
JQA Partners, Inc.  
jabraham@jqapartners.com  
(917) 885-7378