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Araclon Biotech Presents Positive Final Results from Phase 2 Clinical Study of ABvac40 Alzheimer's vaccine at CTAD

- ***Trial met primary endpoints, confirming vaccine's safety, tolerability and robust immune response against the Aβ40 peptide in early-stage Alzheimer's patients***
- ***ABvac40 treatment slowed disease progression up to 38% compared with placebo as measured by the Mini-Mental State Examination score***
- ***Vaccine's unique design offers a new approach to address growing need for effective Alzheimer's treatments as the prevalence of Alzheimer's disease is expected to double by the year 2050 in the U.S. alone[1]***

Zaragoza, Spain, October 25, 2023 – Araclon Biotech, a Grifols Group company dedicated to the research and development of therapies and diagnostic methods applied to neurodegenerative diseases, today announced encouraging final results from its Phase 2 trial (NCT03461276) of ABvac40, an active vaccine against the Aβ40 peptide, for the treatment of patients with early-stage Alzheimer's disease (AD). Araclon gave a late-breaking presentation at the 2023 Clinical Trials on Alzheimer's Disease (CTAD) conference.

Results show that ABvac40 had a favorable safety profile, elicited a robust immune response against Aβ40, and demonstrated some potential cognitive benefits in early-stage AD patients, meeting primary endpoints and showing differences between the vaccine- and placebo-treated groups in some secondary exploratory endpoints.

Data confirm preliminary findings indicating a comparable safety profile between ABvac40 and placebo groups, with similar rates of treatment-emergent adverse events. Specifically in the treatment group there were no reports of swelling (ARIA-E) or aseptic meningo-encephalo-myelitis, and few instances of micro-hemorrhages (ARIA-H) comparable to placebo and none leading to discontinuation.

ABvac40 is uniquely designed to target the C-terminal end of the Aβ40 peptide, thus believed to prevent harmful reactions and avoid immune triggers responsible for meningoencephalitis, a complication observed in earlier AD vaccines. Emerging research suggests that Aβ40 plays a role in cerebral amyloid angiopathy (CAA), a highly prevalent condition among the growing number of AD patients. According to estimates by the Alzheimer's Association, the number of patients with Alzheimer's disease is expected to double by the year 2050 in just the U.S., from 6.7 million in 2023.[1]

[1] Alzheimer's Association. (2023). Alzheimer's Disease Facts and Figures. Retrieved from https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf

Notably, although the trial was not powered for finding efficacy on neuropsychological scales, the ABvac40-treated group exhibited as much as a 38% reduction in disease progression, as reflected by the Mini-Mental State Examination (MMSE) score, suggesting ABvac40's potential efficacy in addressing the cognitive decline associated with AD.

Other neuropsychological tests, such as the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) or the Trial Making Test (TMT), showed favorable results on ABvac40 versus the placebo group. Global or functional scales did not show differences of ABvac40 group vs placebo group. In addition, volumetric magnetic resonance imaging showed a lesser increase in whole brain atrophy in the ABvac40 group vs placebo.

"We are pleased to report final positive results from the Phase 2 study of ABvac40, including a robust immune response with some significant reduction in disease progression, all with a favorable safety profile," said Jose Terencio, Ph.D., Araclon chief executive officer and vice president of Grifols Innovation and New Technologies. "Previous vaccines in development for AD faced setbacks due to harmful meningoencephalitis side effects. The results reported for ABvac40 to date validate its clinical potential, positioning it as promising therapeutic candidate for early AD treatment. We look forward to evaluating next steps for this program."

Mercè Boada Rovira, M.D., Ph.D., co-founder and medical director of the Ace Alzheimer Center in Barcelona and principal investigator of the study, added, "Despite recent treatment developments, there is a large unmet need for disease-modifying therapies for the increasingly growing population of AD patients, particularly in the management of early stages of the disease. By specifically targeting the Aβ40 peptide, ABvac40 is tapping into a central mechanism believed to drive cognitive decline with potential to alter the course of disease."

About the Phase 2 trial

ABvac40 was studied in a multicenter, randomized, double-blind, placebo-controlled Phase 2 trial (NCT03461276) conducted across 23 sites in the EU, to investigate safety, tolerability and immunogenicity of repeated subcutaneous injections of ABvac40 in patients with amnestic mild cognitive impairment (a-MCI) or very mild Alzheimer's Disease (AD). The study was divided into two parts with a total enrollment of 134 patients. In Part-A (18-24 months), patients were randomized to receive a total of six doses, including one monthly single-dose injection of ABvac40 or placebo for the first five months, followed by a delayed booster of ABvac40 or placebo at month 10. Part-B (18 months) was an extension study with cross-over of treatment from Part-A, in which placebo patients at Part-A received ABvac40, and ABvac40-treated patients received placebo and a booster of ABvac40. Primary endpoints were immunogenicity, safety, and tolerability. Safety was assessed as the incidence of treatment-emergent adverse events (TEAEs), serious TEAEs (TESAEs) and TESAEs of special interest, including sulcal effusion and parenchymal edema (ARIA-E), microhemorrhages hemosiderin and deposition (ARIA-H) and aseptic meningo-encephalo-myelitis. Secondary endpoints, assessed at several time points across Part-A, were neuropsychological tests, AD biomarkers in cerebrospinal fluid, cortical fibrillary amyloid deposition, and brain volumetric analysis.

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About Araclon Biotech

Araclon Biotech specializes in researching and developing therapies and diagnostic methods for Alzheimer's disease (AD) and other neurodegenerative diseases. The company, in which Grifols holds a stake of almost 76%, focuses on two research areas: the early diagnosis of AD by means of detecting amyloid-beta peptides in the blood, and the treatment of the disease using immunotherapy (vaccines).

About Grifols

Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world. A leader in essential plasma-derived medicines and transfusion medicine, the company develops, produces and provides innovative healthcare services and solutions in more than 110 countries.

Patient needs and Grifols' ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive the company's innovation in both plasma and other biopharmaceuticals to enhance quality of life. Grifols is focused on treating conditions across a broad range of therapeutic areas: immunology, hepatology and intensive care, pulmonology, hematology, neurology and infectious diseases.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with over 390 across North America, Europe, Africa and the Middle East and China.

As a recognized leader in transfusion medicine, Grifols offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion, in addition to clinical diagnostic technologies. It provides high-quality biological supplies for life-science research, clinical trials, and for manufacturing pharmaceutical and diagnostic products. The company also supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 24,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2022, Grifols' economic impact in its core countries of operation was EUR 9.6 billion. The company also generated 193,000 jobs, including indirect and induced.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE:GRF). Grifols non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ through ADRs (NASDAQ:GRFS).

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