

Grifols presents additional encouraging Alzheimer's trial results at AAIC

New data shows positive impact of AMBAR treatment on efficacy endpoints combining cognition and function in all patients treated

The results are in line with the ones presented in CTAD in Barcelona and AD/PD in Lisbon

Barcelona (Spain), July 16, 2019.- The Grifols Clinical Research team, led by Dr. Antonio Páez, today presented additional results of its AMBAR (Alzheimer Management by Albumin Replacement) clinical trial for the treatment of Alzheimer's at the Alzheimer's Association International Conference (AAIC) 2019 in Los Angeles (USA).

The first results were presented at the 11th Clinical Trials on Alzheimer's Disease (CTAD) Conference in Barcelona (Spain) in October 2018 and at the 14th International Congress on Alzheimer's and Parkinson's (AD/PD) in Lisbon (Portugal) in March 2019.

These results showed a statistically significant reduction of 61% in disease progression in both primary efficacy endpoints, ADAS-Cog (Alzheimer's Disease Assessment Scale – cognitive) and ADCS-ADL (Alzheimer's Disease Cooperative Study – Activities of Daily Living) scales, in the cohort of moderate patients. Regarding specific cognitive aspects, the AMBAR treatment showed positive effects on memory in the moderate patients, and on language and processing speed in patients with the disease in a mild stage.

The additional results presented today at the AAIC point in the same direction in all treated groups across the different relevant endpoints that combine assessments of cognitive status and daily functioning: Clinical Dementia Rating – Sum of Boxes (CDR-Sb) and Alzheimer's Disease Cooperative Study – Clinical Global Impression of Change (ADCS-CGIC).

In particular, the CDR-Sb scale — which assesses memory, orientation, judgment, community affairs, home and hobbies, and personal care — shows a statistically significant 71% less decline with respect to placebo in patients treated as a whole. This significance remains when analyzing the three study treatment arms separately, with less decline at 14 months that ranged 65-71%.

Analysis of mild and moderate cohorts displays a statistically significant less decline of 53% in moderate patients and a statistically significant improvement in mild ones, suggesting that for this endpoint the effect of the treatment might be higher in earlier phases of the disease.

For the ADCS-CGIC scale, which assesses several domains of cognition, daily functioning and behavior from both the patient and the caregiver perspective, the results are in line with those of the CDR-Sb scale: a statistically highly significant stabilization is observed in all treated patients with respect to placebo. This effect remains in all three treatment arms when analyzed separately.

As in the case of CDR-Sb scale, the positive and statistically significant effect is also observed for ADCS-CGIC in the moderate-patient cohort. Moreover, there's a remarkable statistically significant improvement in the mild-patient cohort when compared with placebo at 14 months of treatment. All these effects are replicated when the three treatment arms are assessed against placebo.

At AAIC, Dr. Páez also shared that the plasma amyloid-beta saw-tooth mobilization pattern observed in earlier clinical trials is similar for both conventional and low-volume plasmapheresis performed in the AMBAR trial. This, reinforces the investigational use of smaller volumes of plasma protein replacement therapies.

These encouraging results strengthen Grifols' commitment in the fight against Alzheimer's disease. A further update with the complete clinical, biomarker and neuroimaging results will be presented at the CTAD in San Diego (USA) in December 2019.

"The new results, together with those presented earlier, show positive effects on the three most important endpoints in Alzheimer's disease trials: cognition, function and the combination of both, which is very unique in Alzheimer's investigation," commented Dr. Antonio Páez, Medical Director of the AMBAR Clinical Program at Grifols. "At Grifols we will continue to work with rigor, prudence and respect towards a disease that affects millions of patients, their families and caregivers around the world."

About AMBAR

AMBAR is an international, multicenter, randomized blinded and placebo controlled, parallel group clinical trial that enrolled patients with mild and moderate Alzheimer's from 41 Treatment Centers in Europe and the United States. The study was designed to evaluate the efficacy and safety of short-term plasma exchange followed by long-term plasmapheresis with infusion of Human Albumin combined with intravenous immunoglobulin in patients with mild and moderate Alzheimer's disease.

AMBAR was designed to evaluate whether the progression of Alzheimer's could be stabilized through plasma exchange, a process that entails periodically extracting plasma and replacing it with a specific albumin solution (Albutein®).

AMBAR is based on the hypothesis that most of the amyloid-beta protein – one of the proteins accumulated in the brains of Alzheimer's patients – is bound to albumin and circulates in plasma. Extracting this plasma may flush amyloid-beta peptide from the brain into the plasma, thus limiting the disease's impact on the patient's cognitive functions. Additionally, Albumin may represent a multi-modal approach to the management of the disease due to its binding capacity, antioxidant, immune modulatory and anti-inflammatory properties.

The AMBAR study included 496 mild and moderate Alzheimer patients, randomized in three treatment groups and one control (placebo) group. The participants were 55-85 years old and the efficacy of treatment was measured by changes in cognition and in daily living activities scores. An independent contract research organization (CRO), oversaw the trial's clinical monitoring phase and managed the data collection and analysis stages. The trial employed a randomized and double-blind design, meaning that neither patients nor evaluators knew whether subjects were receiving the treatment or the placebo.

The company began its research on Alzheimer's disease in 2004 with several pre-clinical trials, two pilot studies and a Phase II clinical trial before launching the AMBAR trial.

Fundació ACE in Barcelona, Spain and the Alzheimer Research Center of the University of Pittsburgh, USA have been instrumental partners in the AMBAR research and in Grifols Alzheimer's program since its initiation in 2004.

For more information on the AMBAR Study and the results presented visit: grifols.com/en/ambar

About Grifols

Grifols is a global healthcare company founded in Barcelona in 1940, committed to improving the health and well-being of people around the world. Its four divisions - Bioscience, Diagnostic, Hospital and Bio Supplies - develop, produce and market innovative solutions and services in more than 100 countries.

As pioneers in the field of the plasma science, Grifols is one of the largest plasma companies, with a growing network of donation centers worldwide. It develops this plasma into essential medicines used to treat rare, chronic and, at times, life-threatening conditions. As a recognized leader in transfusion medicine, Grifols also offers a comprehensive portfolio of solutions designed to enhance safety from donation through transfusion. And the company supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 21,000 employees in 30 countries, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership in the industry.

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).

For more information, please visit grifols.com

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