

## Grifols presents new data to support the effectiveness of its clinical trial to treat Alzheimer's

*The latest results show that both mild and moderate patients improve after treatment with the AMBAR protocol*

**Barcelona (Spain), March 29, 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 14th International Congress on Alzheimer's and Parkinson's (AD/PD) in Lisbon (Portugal). Their results were initially presented at the 11th CTAD Congress (Clinical Trials on Alzheimer's Disease) in Barcelona last October.

These additional results complement and confirm those presented in October, not only for patients with moderate-phase Alzheimer's disease, but also for patients in the mild phase of the disease.

From these results we can deduce a relationship between the response of patients and the dose of albumin and immunoglobulin used in protein replacement after the plasmapheresis treatment. Of the three different treatment arms, and in view of the analyzed data, it appears that the treatment that shows the greatest efficacy is the one combining the highest doses of albumin and intravenous immunoglobulin, a result which was predicted by the initial hypothesis on the role of albumin and immunoglobulin in the treatment.

A positive effect of the treatment is observed in all the cognitive aspects analyzed so far in the clinical trial, for all patients, both mild and moderate, treated as a whole. In addition, in some relevant areas, such as language and processing speed, not only is a slowdown in disease progression demonstrated, but there is a statistically significant improvement compared to patients in the placebo group, who exhibit the impairment of the disease itself.

Also, in patients with moderate phases of the disease who were analyzed separately, the area that presents more positive results is memory. Patients with mild phases of the disease show clear improvements in language and processing speed. These results translate into a significant improvement in the quality of daily life of Alzheimer's patients.

These encouraging results for the treatment of Alzheimer's strengthen Grifols' commitment in the fight against Alzheimer's disease, and even more so now, after the withdrawal of other clinical trials on Alzheimer's. Grifols will continue its line of research in this field.

Grifols plans to offer updates for the remainder of 2019, specifically at the AAIC (Alzheimer's Association International Conference) in Los Angeles (USA) in July, and at the CTAD (Clinical Trials on Alzheimer's Disease) in San Diego (USA). In December, all the analyzes mentioned in the study will be available.

"The results that have been presented to date are very encouraging and confirm our line of research. At Grifols we will continue to work with prudence and respect towards a disease that affects millions of patients and family members around the world," commented Dr. Antonio Páez, Medical Doctor of the AMBAR Clinical Program at Grifols.

## ABOUT AMBAR

AMBAR is an international, multicenter, randomized blinded and placebo controlled, parallel group clinical trial that enrolled mild and moderate Alzheimer patients 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 AD.

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:

<https://www.grifols.com/en/ambar>

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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](http://grifols.com)