

Results of Grifols' AMBAR clinical trial published in *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*

- *A group of independent experts from the influential peer-reviewed journal has evaluated Grifols' AMBAR results (Alzheimer Management by Albumin Replacement)*
- *Previously presented at various medical congresses, AMBAR findings demonstrate a slowdown in the progression of symptoms in patients with mild-to-moderate Alzheimer's*
- *The publication reflects more than 15 years of Grifols' research and confirms the potential for plasma therapies to address high-prevalence diseases*

Barcelona, Spain, July 27, 2020 – *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*, the prestigious peer-reviewed scientific journal, today has published the results of Grifols' AMBAR study. This clinical trial was designed to assess the effects of plasma protein replacement therapy in patients experiencing either mild or moderate stages of Alzheimer's disease (AD).

The findings of the AMBAR clinical trial demonstrate a delay in the cognitive and functional decline in AD patients when their plasma is replaced with albumin and immunoglobulin (plasma-derived proteins) following the process of plasma extraction, using the plasmapheresis technique. The results reveal a positive impact in reducing the progression of Alzheimer's symptoms in patients treated over a 14-month period compared to untreated patients.

According to Dr. Antonio Páez, Grifols' medical director of the AMBAR clinical program and one of the main authors of the article, *"These findings are very encouraging. Their publication in one of the most influential journals in the field underscores the relevance of Grifols' research over the last 15 years and its innovative new approach in the fight against Alzheimer's."*

The results of the clinical trial's primary endpoints were supported by those obtained in the most relevant secondary endpoints, in which similar effects were observed. In addition, the clinical trial has shown that plasma exchange is a perfectly feasible protocol in the patient population studied.

According to Eduardo Herrero, president of the Bioscience division industrial group of Grifols, *"This publication leads the way on the future development of plasma protein replacement therapies. At Grifols, we continue our efforts to expand their possibilities so that thousands of patients can benefit."*

The findings now published are the result of rigorous scientific research and reinforce the potential of plasma therapies to treat complex diseases.

Grifols will continue its research on the applications of plasma-derived treatments in parallel with its commitment to develop a therapy to treat Alzheimer's and other degenerative diseases.

About AMBAR

AMBAR is an international, multicenter, randomized, double-blind, placebo-controlled, with parallel assignment clinical trial that enrolled patients with mild and moderate Alzheimer's from 41 treatment centers in Spain 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 albumin combined with intravenous immunoglobulin.

AMBAR was designed to evaluate whether the progression of Alzheimer's could be stabilized through therapeutic plasma exchange, a process that entails periodically extracting plasma and infusing albumin solution (Albutein®) with or without intravenous immunoglobulin (Flebogamma® DIF).

AMBAR targets a multimodal approach to the management of the disease 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.

The AMBAR study included 496 patients aged 55 to 85 years, randomized in three treatment groups and one control (placebo) group. 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.

Grifols began its research on Alzheimer's disease in 2004 with several preclinical 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, PA, USA, have been instrumental partners in the AMBAR research and in Grifols Alzheimer's program since its initiation in 2004.

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. Its four divisions – Bioscience, Diagnostic, Hospital and Bio Supplies – develop, produce and market innovative solutions and services that are sold in more than 100 countries.

Pioneers in the plasma industry, Grifols operates a growing network of donation centers worldwide. It transforms collected plasma into essential medicines 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 to transfusion. In addition, the company 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 30 countries, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2019, Grifols' total socio-economic impact in the main countries where it operates is estimated at 8.5 billion euros and 148,000 jobs generated including direct, indirect and induced employment.

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 www.grifols.com

For further information on AMBAR study: <https://www.grifols.com/en/ambar>

The scientific article is available at: Boada, M., López, O.L., Olazarán, J., Núñez L., Pfeffer, M., Paricio, M., et al. (2020). A randomized, controlled clinical trial of plasma exchange with albumin replacement for Alzheimer's disease: Primary results of the AMBAR Study. *Alzheimer's Dement.* <https://doi.org/10.1002/alz.12137>

INVESTORS

Investors Relations Department

inversores@grifols.com - investors@grifols.com

Tel. +34 93 571 02 21

MEDIA

Media Press Office

media@grifols.com

Tel. +34 571 00 02

International media contact

grifols@hkstrategies.com

Tel. +44 7342 067936

Spain media contact - Duomo Comunicación

grifolsmedia@duomocomunicacion.com

Tel. +34 659 57 21 85

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