

## **Grifols announces topline data from NIAID Phase 3 ITAC trial (INSIGHT-013) evaluating hyperimmune globulins as a treatment for hospitalized patients with COVID-19**

*Grifols continues its COVID-19 research, with more than 20 initiatives targeting different disease stages*

**Barcelona, Spain, April 2, 2021** - Grifols (MCE: GRF, MCE: GRF.P, NASDAQ: GRFS), a global leader in the development of plasma-derived medicines with a track record of more than 100 years dedicated to enhancing people's health and well-being, today announced that the Phase 3 Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) clinical trial, also known as INSIGHT-013, sponsored and supported by the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), did not meet its primary endpoints with statistically significant results.

The company will continue to move forward with its work on more than 20 research initiatives to find potential treatment options for different stages of COVID-19.

Regarding treatment of early-stage COVID-19 to halt disease progression, Grifols has a multifaceted approach. It will participate in an international study in collaboration with the NIAID and NIH to test an intravenous anti-SARS-CoV-2 hyperimmune globulin in outpatients. The company will also evaluate, in a study in Spain, a subcutaneously administered anti-SARS-CoV-2 hyperimmune globulin for asymptomatic outpatients, and is participating, also in Spain, in a clinical study to test convalescent plasma as early treatment in non-hospitalized mild or moderate COVID-19 patients.

Grifols is also evaluating the impact of other plasma-derived treatments such as alpha-1 antitrypsin, immunoglobulins and antithrombin III on COVID-19 patients in various disease stages to mitigate the effects of the infection.

Grifols thanks all of those involved in the ITAC clinical trial, especially the recovered COVID-19 donors who provided their plasma for the intravenous anti-SARS-CoV-2 hyperimmune globulin, as well as Grifols frontline workers for answering the call during very difficult times.

The project has been funded in part with federal funds from the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, through the Department of

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Defense's Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, Medical CBRN Defense Consortium OTA No. W15QKN-16-9-1002.

## About the ITAC Trial

The Phase 3 Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) clinical trial is a global, multi-center, double-blind, placebo-controlled, randomized trial sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). It is designed to test the safety, tolerability and efficacy of a combination treatment regimen for coronavirus disease 2019 (COVID-19) consisting of the antiviral remdesivir along with an anti-SARS-CoV-2 hyperimmune intravenous immunoglobulin, which contains a highly concentrated solution of antibodies that neutralize SARS-CoV-2. The antibodies in the anti-SARS-CoV-2 hyperimmune globulin come from the liquid portion of blood, or plasma, donated by healthy people who have recovered from COVID-19.

Through the NIAID-funded INSIGHT network, the study team enrolled nearly 600 adult patients at 67 sites in the United States and 10 other countries on five continents. Volunteers were eligible for the trial if they had been hospitalized for COVID-19 and had symptoms for 12 days or fewer without life-threatening organ dysfunction or end-organ failure. Four companies provided investigational anti-SARS-CoV-2 hyperimmune globulin materials for the trial, including CSL Behring and Takeda on behalf of the CoVlg-19 Plasma Alliance, as well as Emergent BioSolutions and Grifols. Further information about the ITAC trial is available at [ClinicalTrials.gov](https://ClinicalTrials.gov) under study identifier [NCT04546581](https://ClinicalTrials.gov/ct2/show/study/NCT04546581).

## 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 chronic, rare 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 nearly 24,000 employees in 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2020, Grifols' economic impact in its core countries of operation was EUR 7.5 billion. The company also generated 140,000 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).

For more information, please visit [www.grifols.com](http://www.grifols.com)

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