

## Grifols' anti-SARS-CoV-2 hyperimmune globulin begins clinical trial in patients with COVID-19

- *The trial, part of a collaboration with U.S. government agencies including BARDA, the FDA and the NIH, will evaluate the safety, efficacy and tolerability of the anti-SARS-CoV-2 hyperimmune globulin that, if proven safe and effective, could be a potential treatment for COVID-19*
- *It's the first international multicenter clinical trial of an anti-SARS-CoV-2 hyperimmune globulin and will include 500 hospitalized adults with COVID-19 in up to 58 hospitals in 18 countries. The therapy comes from the convalescent plasma of healthy people who have recovered from the disease*
- *Grifols is also leading or participating in more than 25 initiatives researching potential treatment options for different COVID-19 disease stages, from patients with mild symptoms who stay at home to hospitalized patients as well as severe cases requiring intensive care*

**Barcelona, Spain, October 9, 2020** - Grifols (MCE: GRF, MCE: GRF.P, NASDAQ: GRFS), a global leader in the development of therapies with plasma-derived proteins with a track record of more than 100 years dedicated to enhancing people's health and well-being, today announced that its anti-SARS-CoV-2 hyperimmune globulin, a potential treatment for COVID-19, has started a randomized controlled clinical trial to test its safety, efficacy and tolerability. This medicine provides a high and consistent concentration of purified neutralizing antibodies and could be used for both prevention and treatment of the disease. The study is sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH).

The start of the clinical trial is the latest phase of an initiative that goes back to March when Grifols started work on its anti-SARS-CoV-2 hyperimmune globulin as part of a collaboration with U.S. government agencies such as the Biomedical Advanced Research Development Authority (BARDA), the Food and Drug Administration (FDA), the NIAID and the NIH. In addition to Grifols, the other manufacturers providing product for the trial are Emergent BioSolutions, CSL Behring and Takeda Pharmaceuticals.

Investigators running the clinical trial want to determine if giving the anti-coronavirus hyperimmune globulin when COVID-19 symptoms first appear, before a person's immune system makes a protective immune response on its own, could augment the natural antibody response to SARS-CoV-2, thereby reducing the risk of more serious illness and death.

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This is the first international multicenter clinical trial of an anti-SARS-CoV-2 hyperimmune globulin, which is randomized double-blind, placebo-controlled and adaptive. Patients will receive either the anti-SARS-CoV-2 hyperimmune globulin and remdesivir, or remdesivir plus placebo.

The Phase 3 trial, called Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC), will include 500 hospitalized adults with COVID-19 in up to 58 hospitals covering 18 countries including the United States and Spain. For the trial Grifols has collected convalescent plasma from healthy recovered COVID-19 donors, in the U.S. using its plasma-center network and in Spain through a collaboration with blood banks.

Grifols has moved quickly to respond to the need for an anti-SARS-CoV-2 hyperimmune globulin. It was the first to mobilize large-scale collection of convalescent plasma, using its industry-leading network of more than 300 plasma-collection centers. It was also the first to manufacture and deliver clinical batches of the anti-SARS-CoV-2 hyperimmune globulin. The company's primed infrastructure is ready to ramp up quickly to produce large volumes of medicine should they be needed.

Grifols is proud to lead or participate in more than 25 initiatives to fight COVID-19. This includes several clinical trials with already existing plasma-derived therapies, such as alpha-1 antitrypsin, immunoglobulins and convalescent plasma, to treat different stages of COVID-19. This includes patients with mild symptoms who stay at home, hospitalized patients and severe cases requiring intensive care.

The anti-SARS-CoV-2 hyperimmune globulin is one of the treatments for patients whose respiratory symptoms require hospitalization but not intensive care. Grifols is also leading studies with alpha-1 antitrypsin and immunoglobulins for hospitalized patients with different disease progression, or requiring intensive care, in the U.S. and Spain.

For patients needing intensive care and treatments that reduce their viral loads, inflammation and respiratory distress, Grifols is sponsoring trials in the U.S. and Spain in which these patients receive convalescent plasma and high doses of intravenous immunoglobulin.

"Grifols has responded with a high sense of urgency to this public health emergency, proudly having established, in a short amount of time, a large-scale convalescent plasma collection program to produce important clinical volumes of an anti-SARS-CoV-2 hyperimmune globulin to treat patients," said Eduardo Herrero, president of Grifols' Bioscience Industrial Division.

"Grifols is very hopeful that all the clinical trials it is leading or participating in across different COVID-19 disease stages will advance as quickly as possible and prove to be successful," said Víctor Grífols Deu, co-CEO of Grifols.

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## 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' economic impact in its core countries of operation was 8.5 billion euros. The company also generated 148,000 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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