

Grifols starts production of its hyperimmune immunoglobulin as a potential passive immune therapy against COVID-19

Grifols continues to lead initiatives to combat COVID-19 with the development of the first specific drug

- Grifols has become the first company to start production of an anti-SARS-CoV-2 hyperimmune immunoglobulin by leveraging its broad expertise and experience in the development of specific immunoglobulins used in the treatment and prevention of infections and that have been applied to healthcare emergencies like the Ebola outbreak
- Grifols is a worldwide leader in the production and sale of immunoglobulins, a plasma protein with proven safety, broad clinical applications and significant therapeutic potential
- Immunoglobulin therapies are mainly used to prevent and treat infections in cases of accidental exposure to infectious agents, primary and secondary immunodeficiencies, neurological conditions associated with autoimmune diseases, and weakened immune systems from cancer treatments

Barcelona, June 11, 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 the start of production of its [anti-SARS-CoV-2 hyperimmune immunoglobulin with specific antibodies](#) using the plasma of people who have overcome the disease. It is the first specific drug developed to combat COVID-19.

Grifols is leading the production of this potential anti-COVID-19 passive immune therapy as part of a collaboration agreement with U.S. government entities, including the Food and Drug Administration (FDA), the National Institutes of Health (NIH) and the Biomedical Advanced Research Development Authority (BARDA), among other healthcare agencies. The agreement also encompasses the development of preclinical and clinical trials required to determine treatment efficacy. The company is also moving forward to establish collaborations in Europe.

Grifols' anti-SARS-CoV-2 hyperimmune immunoglobulins are being produced in its Clayton (North Carolina, U.S.) facility, which has been specifically designed to process specialty immunoglobulins.

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The first doses are expected to be available in July 2020 as part of a clinical trial.

Grifols leverages its broad expertise and experience in previous healthcare emergencies like the Ebola outbreak to become the first company to start production of an anti-SARS-CoV-2 hyperimmune immunoglobulin.

At the same time, Grifols is moving forward with its clinical trial in Spain to assess the effectiveness of [high-dose intravenous immunoglobulin to stabilize or improve the condition of COVID-19 patients](#).

In this regard, the trial aims to assess the action of neutralizing antibodies (proteins that bind viruses and prevent them from infecting human cells), as well as determine the immunomodulatory potential (immune modulation response) of immunoglobulins as therapy to block the cytokine storm in patients with severe cases of COVID-19.

Immunoglobulins: plasma proteins with a broad therapeutic potential and complex action mechanisms that are difficult to replicate

Immunoglobulins are plasma proteins that act like antibodies as part of the body's defense system, with complex and hard-to-replicate mechanisms of action.

Thanks to their broad scope of action - including their immunomodulatory effects - immunoglobulins have a vast and varied range of clinical applications, such as the prevention of infection in immunodeficient patients and autoimmune diseases, both neurological and in other organs.

Treatment with immunoglobulins is essential in the prevention of infections in the event of accidental exposure to infectious agents such as Hepatitis B or the Rabies virus. They are also essential in the prevention of infections in patients with [primary immunodeficiencies \(PID\)](#), which include more than 300 diseases, 150 of which stem from a congenital defect. These diseases are the result of a quantitative and/or functional alteration of the various mechanisms involved in the immune response.

Immunoglobulin has also been proven as a safe and effective treatment for a number of [neurological diseases](#), including Guillain Barré syndrome, chronic inflammatory demyelinating polyneuropathy (CIDP), multifocal motor neuropathy, myasthenia gravis, and Lambert-Eaton syndrome, among others.

These highly complex diseases are difficult to treat without intravenous immunoglobulin due to limitations in reproducing all of their mechanisms of action, which are the result of the natural evolution of the human immune system.

With broad therapeutic potential, immunoglobulins are also used to treat [secondary immunodeficiencies](#), which occur when a disease or therapeutic treatment decreases the

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immune cells' ability to react against pathogens and form antibodies, requiring that part of the immune system to be replaced.

This type of immunodeficiency can also appear in autoimmune diseases like rheumatoid arthritis, lupus and multiple sclerosis as a consequence of the use of immunosuppressive drugs. Treatments for diseases such as cancer may also lead to weakened immune systems. Thus, research is currently underway to discover new immunotherapy and immunoglobulin strategies for cancer patients.

At present, there are more than 5,000 clinical trials¹ around the world to further explore the treatment potential of this plasma protein.

Grifols is the worldwide leader in the production and sale of immunoglobulins and remains firmly committed to addressing the current and future needs of patients in need of this plasma protein thanks to the generosity of its donors.

Strong growth forecast for immunoglobulins in 2019-2022

According to the Marketing Research Bureau (MRB), the immunoglobulin market will continue to grow annually by a high single digit in the 2019-2022 period.

Advancements in immunotherapies are expected to spark higher demand for immunoglobulins during this period. Therapies like CAR-T cells could create a growing need for these plasma proteins in the field of secondary immunodeficiencies.

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¹ Source: www.clinicaltrials.gov

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.

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

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