# **GRIFOLS**

# Grifols Announces Formal Collaboration with US Government to Produce the First Treatment Specifically Targeting COVID-19

Barcelona, March 25, 2020 – Grifols today announces that it has entered into a formal collaboration with the United States Biomedical Advanced Research Development Authority (BARDA), the Food and Drug Administration (FDA) and other Federal public health agencies to collect plasma from convalescent COVID-19 patients, process this specific plasma into a hyperimmune globulin and support the necessary preclinical and clinical studies to determine if anti-SARS-CoV-2 hyperimmune globulin therapy can successfully be used to treat COVID-19 disease. Grifols will volunteer its expertise and resources in the areas of plasma collection using its network of FDA-approved plasma donor centers; test and qualify donors in conjunction with other health agencies; process plasma into hyperimmune globulin in its purpose-built facility in Clayton, North Carolina, for the isolated processing of immune globulins to treat emerging infectious diseases; and support preclinical and clinical studies to determine whether hyperimmune globulin made from the plasma of convalescent donors can live up to its promise as a viable treatment for COVID-19 disease and as a platform for the treatment of future emerging infectious diseases.

This innovative public-private partnership presents opportunities to expedite development and, if successful, availability of a front-line therapeutic in the face of the spreading COVID-19 pandemic. The FDA is specifically working to reduce unnecessary regulatory hurdles and ensure a rapid turnaround without compromise to product safety or integrity.

As indicated by FDA Commissioner Stephen Hahn, M.D., during the President's March 19 Coronavirus Task Force briefing, "There is a cross agency effort about...convalescent plasma. This is an exciting area...If you've been exposed to coronavirus and you are better...we could collect the [plasma], concentrate that...to be able to give that to other patients. The immune response could provide a benefit to patients."

In addition to the development of a hyperimmune globulin as a therapy for COVID-19, Grifols is also providing support to utilize convalescent plasma for transfusion as a potential therapy by providing viral inactivation technology (methylene blue) to ensure inactivated plasma units for treatment use. (Grifols will be building a new facility in the Clayton site for this purpose.)

At Grifols we believe this current and extraordinary situation requires companies to strive more than ever to serve patients and society around the world and is proud to be working with the United States Public Health Agencies and personnel to combat COVID-19 disease.

This unique collaboration will provide the opportunity to validate a therapy that, if proven effective, can be used today in the face of the COVID-19 pandemic and for future outbreaks of novel emerging viruses.

At the same time, in Spain Grifols is working on a clinical trial with inactivated plasma from recovered patients (methylene blue) through a collaboration with select donation centers and public hospitals since, unlike in the U.S., in Spain there are no Grifols-owned plasma donation centers. In addition, the company is collaborating with certain hospitals in the design of diverse clinical studies on the use of certain plasma-derived products, such as intravenous



immunoglobulin and alpha-1 antitrypsin, with the goal of proving their efficacy in the treatment of COVID-19.

In addition, Grifols has accelerated the development and validation of a proprietary technology TMA (transcription-mediated amplification) based diagnostic procedure, able to detect the virus with a sensitivity equivalent or even superior to that of PCR (polymerase chain reaction). The test will be performed on automatic instrumentation, with each machine able to run more than 1,000 samples per day, and that will be ready in the following weeks.

We are very thankful to our Grifols employees for their efforts in these unsettling times, and especially grateful to our donors for continuing to donate plasma, helping us all to make a difference.

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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.



The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the lbex-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: www.grifols.com

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