

## **GigaGen Publishes Research Showcasing First-Ever Clinical GMP Manufacturing and IND-Enabling Studies for its New Class of Drugs, Recombinant Polyclonal Antibodies**

South San Francisco, Calif., July 28, 2022 (GLOBE NEWSWIRE) -- [GigaGen Inc.](#), a biotechnology company advancing transformative antibody drugs for immune deficiencies, infectious diseases and checkpoint resistant cancers, and a subsidiary of [Grifols](#), announced today the publication of a research article titled, "[GMP manufacturing and IND-enabling studies of a recombinant hyperimmune globulin targeting SARS-CoV-2](#)," in the international, peer-reviewed journal *Pathogens*. This work showcases for the first time the GMP (good manufacturing practice) manufacturing and IND (Investigational New Drug)-enabling studies of its new class of drugs, recombinant polyclonal antibodies, describing the company's recombinant polyclonal product that targets SARS-CoV-2, GIGA-2050.

GIGA-2050 is comprised of more than 12,000 antibodies but produced from a single master cell bank (MCB). Prior to GIGA-2050, manufacturing methods for much smaller mixtures of recombinant antibodies often involved the creation of separate MCBs for each monoclonal antibody, followed by mixing the MCBs prior to manufacturing. GIGA-2050 material produced at scales ranging from 3L to 250L had high product quality and consistent yield and potency. Through *in vivo* studies, GIGA-2050 was shown to be safe and protective against SARS-CoV-2 infection.

Carter Keller, a senior vice president at Grifols and head of GigaGen, commented, "GigaGen's recombinant polyclonal drugs are a new approach to treating infectious diseases, in particular those best treated by targeting multiple viral epitopes. Our novel manufacturing approach allows us to consistently produce drugs consisting of thousands of antibodies against a virus. We look forward to continuing to leverage our cutting-edge technology and this new class of drugs for the development of medicines for multiple infectious diseases with large unmet need, including our ongoing program for the treatment of the hepatitis B virus (HBV), an infectious disease affecting more than 290 million people worldwide."

### **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. A leader in essential plasma-derived medicines and transfusion medicine, the company develops, produces and provides innovative healthcare services and solutions in more than 110 countries.

Patient needs and our ever-growing knowledge of many chronic, rare and prevalent diseases, sometimes life-threatening, drive our innovation in plasma-based therapies and other biopharmaceuticals to enhance quality of life. Grifols is focused on treating conditions across a broad range of therapeutic areas: immunology, hepatology and intensive care, pulmonology, hematology, neurology and infectious diseases.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with over 400 across North America, Europe, Africa and the Middle East and China.

As a recognized leader in transfusion medicine, Grifols offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion, in addition to clinical diagnostic technologies. We provide high-quality biological supplies for life-science research, clinical trials, and for manufacturing pharmaceutical and diagnostic products. 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 23,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety, and ethical leadership.

In 2021, Grifols' economic impact in its core countries of operation was EUR 7.7 billion. The company also generated 141,500 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).

GigaGen is advancing transformative antibody drugs for immune deficiency, infectious diseases and checkpoint resistant cancers by leveraging industry-leading, single-cell technologies. Its novel technology platforms uniquely capture and recreate complete immune repertoires as functional antibody libraries. This approach has enabled the creation of first-in-class recombinant polyclonal antibody therapies for the treatment of infectious diseases. In addition, GigaGen's lead oncology asset, GIGA-564, is an anti-CTLA-4 monoclonal antibody that has demonstrated improved anti-tumor efficacy in vivo through a unique mechanism of action.

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

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