

GigaGen Publishes Research on Company's Recombinant Hyperimmunes in Nature Biotechnology

Article describes GigaGen's technology and approach for the production of a new class of drug, recombinant hyperimmunes, including its novel COVID-19 therapy

South San Francisco, Calif., April 15, 2021 (GLOBE NEWSWIRE) -- [GigaGen Inc.](#), a biotechnology company advancing transformative antibody drugs for infectious diseases, transplant rejection and checkpoint resistant cancers, and a subsidiary of [Grifols](#), announced today publication of research, titled, "Generation of recombinant hyperimmune globulins from diverse B cell repertoires," in the peer-reviewed journal *Nature Biotechnology*. The data describes GigaGen's proprietary technology for the production of a new class of antibody drug, "recombinant hyperimmune globulins," which include its novel COVID-19 therapy, GIGA-2050. This program recently received an Investigational New Drug (IND) approval by the U.S. Food and Drug Administration (FDA) for the initiation of a Phase 1 clinical trial. A previous version of the data was made available through bioRxiv.

"The peer-reviewed publication of our research in the prestigious journal Nature Biotechnology demonstrates the novelty of our technology and validates its application to develop a completely new class of drug, recombinant polyclonal antibody products, such as recombinant hyperimmune globulins," said David Johnson, Ph.D., CEO of GigaGen. "We look forward to evaluating our first recombinant hyperimmune globulin in the clinic for COVID-19 patients this year and continuing to leverage our technology and approach to advance multiple recombinant hyperimmune candidates we believe could overcome treatment challenges for many infectious diseases and primary immune deficiencies."

The article demonstrates that GIGA-2050 comprises more than 12,000 antibodies against natural SARS CoV-2 variants. Additionally, the publication shows proofs-of-concept for other polyclonal drugs, including a Zika hyperimmune, a high-potency spike-in intravenous immunoglobulin (IVIG)-mixture for primary immune deficiency and a recombinant version of ATG for transplant tolerance. The data also demonstrates the drugs can be produced with exceptionally high batch-to-batch consistency.

"Nature Biotechnology's inclusion of GigaGen's research centered on establishing the next generation of antibody treatments, including a recombinant hyperimmune globulin as a potential treatment for COVID-19, underscores the exceptional technology and approach as well as Grifols' growing innovation portfolio," said Jose Terencio, Grifols Vice President of Innovation.

About GIGA-2050

GIGA-2050 is a new class of drug designed to provide passive immunity to COVID-19 patients or those at high risk. It can be described as "recombinant convalescent serum," in that it has the consistency, purity and potency of recombinant antibodies, while capturing and enhancing the diversity of anti-coronavirus antibodies observed in convalescent serum. Unlike current recombinant antibody therapies in development for COVID-19 that comprise one or a few antibodies against specific epitopes of the SARS CoV-2, GIGA-2050 comprises more than 12,000 antibodies with strong binding activity against natural SARS CoV-2 variants. To produce GIGA-2050, GigaGen captured millions-diverse antibody sequences from B cell repertoires of 16 convalescent donors with exceptionally strong antibody responses to COVID-19. Thousands of select libraries have been engineered into mammalian cell line clones to produce the antibody product at large scale.

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](#)).

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, including GigaGen's lead asset GIGA-2050 for COVID-19. 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 or www.gigagen.com.

Media Contacts:

Monica Rouco Molina, Ph.D.
LifeSci Communications
+1-929-469-3850
mroucomolina@lifescicomms.com

Grifols Media Press Office

media@grifols.com
Tel. +34 571 00 02

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