GigaGen Doses First Patient in Phase 1 Trial of Recombinant Hyperimmune Polyclonal Antibody GIGA-2050 for COVID-19

First-in-human study evaluating recombinant hyperimmunes

South San Francisco, Calif., August 11, 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 the first patient has been dosed in its Phase 1 clinical trial of GIGA-2050, the company's recombinant hyperimmune polyclonal antibody drug designed to provide passive immunity to COVID-19 patients.

GIGA-2050 is comprised of more than 12,000 antibodies demonstrating strong neutralizing activity against natural SARS CoV-2 variants in laboratory studies, including the delta variant and other variants that have emerged globally since the beginning of the pandemic. GIGA-2050 encompasses the full diversity of anti-coronavirus antibodies captured from the convalescent serum of 16 exceptional responders to COVID-19.

"The initiation of GigaGen's first Phase 1 clinical trial marks a significant milestone for the company, as the first clinical evaluation of our recombinant polyclonal hyperimmunes," said David Johnson, Ph.D., co-founder and chief executive officer of GigaGen. "Unlike monoclonal antibodies, GIGA-2050 binds to thousands of viral epitopes. As a result, GIGA-2050 has strong neutralizing activity against every variant we've ever tested in the lab, including the delta variant. The information obtained from the trial will not only contribute to the advancement of our COVID-19 program but will also provide initial clinical safety validation for this new class of therapeutics."

The Phase 1 single ascending dose (SAD) clinical trial is designed to assess the safety and tolerability of GIGA-2050 in up to 18 hospitalized patients with confirmed COVID-19. Participants will be divided into three cohorts who will receive a single intravenous (IV) infusion dose of GIGA-2050 at 5mg, 15mg or 50 mg (or as determined by the safety review committee) per kg of body weight, respectively. Participants will be followed for safety, pharmacology and efficacy assessments during hospitalization, after discharge (if applicable), and through study discontinuation or end of study visit at day 56. For more information about the trial, refer to clinicaltrials.gov identifier: NCT04883138.

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 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 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.

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