

GigaGen Doses First Patient in Phase 1 Trial of Recombinant Polyclonal Drug Candidate, GIGA-2339, for Hepatitis B Virus

GIGA-2339 contains more than 1,000 fully human recombinant anti-HBV antibodies and is the first recombinant polyclonal therapeutic in development to treat and functionally cure chronic HBV infection

San Carlos, Calif., November 19, 2024 (GLOBE NEWSWIRE) -- [GigaGen Inc.](#), a biotechnology company advancing transformative antibody drugs for immunodeficiencies, infectious diseases and checkpoint-resistant cancers, and a subsidiary of [Grifols](#), announced today that the first patient has been dosed in a Phase 1 clinical trial evaluating the safety and tolerability of the first recombinant polyclonal drug candidate, GIGA-2339, for the treatment of hepatitis B virus (HBV) infection.

“The initiation of this Phase 1 trial with GIGA-2339 represents a milestone in our mission to develop the next generation of antibody drugs for addressing infectious disease treatment,” said Carter Keller, senior vice president of Grifols and head of GigaGen. “With more than 1,000 anti-HBV antibodies and a potency over 2,000 times higher than other HBV drugs, GIGA-2339 is the first therapeutic of its kind to treat and functionally cure chronic HBV infection. It is unlike any other therapy currently in development. By harnessing the precision of these antibodies, it targets the large diversity of circulating HBV variants, offering a more targeted and effective solution with potential to bring new hope to millions affected by this chronic disease.”

The Phase 1 dose escalation clinical trial is designed to assess the safety and tolerability of GIGA-2339 in patients with confirmed chronic HBV infection. GIGA-2339 is the clinical lead of GigaGen’s growing recombinant polyclonal antibody [pipeline](#). GigaGen’s recombinant polyclonals are part of Grifols’ robust innovation strategy and commitment to delivering the next generation of antibody drugs for patients and healthcare professionals.

About HBV infection

Despite currently available therapies and vaccines, HBV affects more than 296 million people worldwide, resulting in more than 800,000 deaths each year.¹ Currently there is no cure, as existing drugs can halt viral replication but only minimally reduce the levels of viral protein.

About GIGA-2339

Developed using GigaGen’s next-generation platform, GIGA-2339 consists of more than 1,000 anti-HBV antibodies developed in the laboratory by capturing and then reproducing the natural antibody response from donors who have been vaccinated against HBV. GIGA-2339 is over 2,000 times more potent than plasma-derived HBV drugs and covers the large diversity of circulating HBV variants. In mouse models, GIGA-2339 neutralized and cleared HBV’s viral DNA along with its antigens. Through this unique mechanism of action, GIGA-2339 has the potential to clear viral particles and activate the immune response to provide functional cure for people living with HBV.

About GigaGen’s platform

GigaGen’s next-generation recombinant polyclonal platform offers a novel way to develop synthetic polyclonal antibody therapeutics in the laboratory, which are more powerful than what a natural immune response can provide. Using high-throughput, single-cell genomic and protein engineering technology, GigaGen creates cell lines that express recombinant human antibodies against a diversity of infectious disease antigens. The polyclonal cell bank can then be used to continuously manufacture recombinant polyclonal products against the pathogen of interest at existing manufacturing facilities. GigaGen has demonstrated that its products are hundreds of times more potent than plasma-derived antibody therapies. They replicate and enhance the natural antibody diversity, encompassing thousands of antibodies. This offers a significant advantage over monoclonal antibody therapies, as they can address the vast diversity of circulating pathogen variants and help prevent immune escape upon pathogen mutation.

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 Grifols' ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive the company's innovation in both plasma and other biopharmaceuticals. The company 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 390 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. It provides high quality biological supplies for life-science research, clinical trials, and for manufacturing pharmaceutical and diagnostic products. The company also 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 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.

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 immunodeficiencies, 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 and reduced toxicities in preclinical models through a unique mechanism of action.

For more information, please visit www.grifols.com or www.gigagen.com.

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¹WHO (<https://www.who.int/news-room/fact-sheets/detail/hepatitis-b>)