GigaGen Receives FDA Clearance of IND Application for Phase 1 Trial of Recombinant Polyclonal for HBV Treatment, GIGA-2339

GIGA-2339 is the first recombinant polyclonal therapeutic in development to treat and functionally cure chronic hepatitis B virus (HBV) infection; trial initiation expected in Q4 2024

Containing more than 1,000 fully human recombinant anti-HBV antibodies, GIGA-2339 reproduces the human body's natural immune response

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

San Carlos, Calif., July 31, 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 United States Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to initiate a Phase 1 trial to evaluate the company's first recombinant polyclonal drug for the treatment of hepatitis B virus (HBV) infection, GIGA-2339.

"FDA clearance of our IND application marks a significant milestone as part of Grifols' commitment to develop transformative antibody drugs for infectious diseases," said Carter Keller, senior vice president of Grifols and head of GigaGen. "Patients experiencing chronic HBV live with ongoing complications and commonly progress to hepatocellular carcinoma and cirrhosis. With over 1,000 different HBV-targeted antibodies in the mixture, GIGA-2339 is unlike any therapy currently in development. We look forward to initiating our trial in late 2024 and showcasing the clinical potential of our recombinant polyclonal antibody platform, starting with HBV."

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.

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.

The Phase 1 dose escalation clinical trial is designed to assess the safety and tolerability of GIGA-2339 in patients with confirmed HBV infection.

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

About GigaGen's platform
GigaGen's next-generation hyperimmune platform offers a novel way to develop recombinant polyclonal antibody therapeutics in the laboratory which are potentially 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, including HBV. The polyclonal cell bank can then be used to continuously manufacture hyperimmune products against the pathogen of interest at existing manufacturing facilities.

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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