

GigaGen Partners with the National Cancer Institute to Advance Oncology Drug Candidate GIGA-564

Collaboration sets stage for GigaGen's first oncology asset to enter clinical development

GIGA-564 is a differentiated anti-CTLA4 antibody with potential to enhance anti-tumor activity and mitigate immune-related toxicities associated with traditional CTLA-4 blockade

GigaGen and NCI will present investigational new drug (IND)-enabling data and clinical trial strategy for GIGA-564 at the 2023 Society for Immunotherapy of Cancer (SITC) Annual Meeting

San Carlos, Calif., September 28, 2023 (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 that it has signed an agreement with the National Cancer Institute (NCI), part of the National Institutes of Health, to advance development of the company's differentiated anti-CTLA-4 antibody drug candidate for cancer treatment, GIGA-564.

This Cooperative Research and Development Agreement enables further preclinical and clinical studies to assess GIGA-564's potential across various tumor types, including the first in-human Phase 1 clinical trial for the drug candidate in advanced solid tumors.

"We are proud to receive the NCI's support and partner with their esteemed clinical research team to drive the GIGA-564 program forward," said Carter Keller, senior vice president of Grifols and head of GigaGen. "GIGA-564 represents a new approach to designing anti-CTLA-4 agents with potential not only to enhance anti-tumor activity but also to mitigate immune-related toxicities typically associated with first generation anti-CTLA-4 therapies. We look forward to continuing to demonstrate its potential in a clinical setting as we plan to file the IND application for our first Phase 1 clinical trial in advanced solid tumors before the end of 2023."

This agreement signifies a milestone for GigaGen, as GIGA-564 could be the company's first oncology candidate to reach clinical stage.

GIGA-564, a fully human monoclonal antibody, distinguishes itself from currently available anti-CTLA-4 drugs. Previous anti-CTLA-4 drugs were designed to strongly block CTLA-4's interaction with its ligands, thereby enhancing T cell co-stimulation. However, this approach has been associated with heightened immune-related side effects.

Moreover, recent insights reveal that previous anti-CTLA-4 drugs contribute to an increased proliferation of T regulatory cells (Tregs), which may dampen their intended effect of activating cytotoxic T cells that are vital for attacking tumors. In comparison, GIGA-564's uniqueness stems from its minimal CTLA-4 blockade and its ability to deplete intratumoral Tregs within the tumor microenvironment. This distinctive mode of action has translated into superior anti-tumor performance and reduced immune-related toxicity in [preclinical models](#), distinguishing it from commercially available anti-CTLA-4 drugs.

The initiative will be spearheaded by distinguished NCI researchers James L. Gulley, M.D., Ph.D. and Jeffrey Schlom, Ph.D., in close partnership with GigaGen's team. The program will draw upon the extensive infrastructure and established scientific and clinical expertise in oncology drug development from the Center for Immuno-Oncology of the NCI Center for Cancer Research. As part of the agreement, the NCI will conduct the Phase 1 clinical study of GIGA-564 in advanced solid tumors. GigaGen will be the IND sponsor and will provide the clinical-grade GIGA-564 material. The NCI will conduct additional preclinical studies and potential clinical studies of GIGA-564 as a monotherapy or in combination with other therapies.



GigaGen and NCI will present IND-enabling data and the clinical trial plan for GIGA-564 at the 2023 SITC Annual Meeting, to be held in San Diego, Calif., on November 1-5, 2023. Presentation details are below:

Title: Non-clinical results and design of First-in-Human study for GIGA-564, a third-generation anti-CTLA-4 monoclonal antibody

Poster #: 1380

Presenter: Erica L. Stone, Ph.D.

Date: Saturday, Nov. 4, 2023

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 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 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.

In 2022, Grifols' economic impact in its core countries of operation was EUR 9.6 billion. The company also generated 193,000 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. 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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