

GigaGen Receives FDA clearance of IND to begin Phase 1 Trial of Oncology Drug Candidate, GIGA-564, in solid tumors

The Phase 1 trial will be conducted by researchers from the National Cancer Institute as part of a Cooperative Research and Development Agreement (CRADA)

GigaGen anticipates trial initiation in 2024

San Carlos, Calif., December 12, 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 the U.S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application to initiate a Phase 1 trial to evaluate the company's oncology candidate, GIGA-564, for the treatment of solid tumors.

"We are pleased to have reached this significant milestone, paving the way for our first oncology asset to enter clinical development," said Carter Keller, senior vice president of Grifols and head of GigaGen. "GIGA-564 introduces a novel approach to CTLA-4 targeting, with the promise of enhanced anti-tumor activity and lower side effects compared with existing anti-CTLA-4 agents. We look forward to initiating the trial in 2024 and translating this potential into tangible clinical outcomes for patients."

In [non-clinical models to date](#), GIGA-564 depleted intratumoral T regulatory cells (Tregs) within the tumor microenvironment, which enables the tumor-killing activity of cytotoxic T cells. It also led to increased anti-tumor efficacy and reduced toxicity compared to the commercially available drug ipilimumab, a monoclonal antibody designed to work through CTLA-4 checkpoint inhibition.

The Phase 1a/1b dose escalation and dose-expansion trial will evaluate GIGA-564 for the treatment of advanced solid tumors. The trial will be conducted by National Institutes of Health's National Cancer Institute (NCI) researchers in close partnership with the GigaGen team.

About GIGA-564

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.

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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