

GigaGen Doses First Patient in Phase 1 Trial of Anti-CTLA-4 Oncology Drug Candidate GIGA-564 in Advanced Solid Tumors

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

Researchers from the National Cancer Institute will conduct the Phase 1 trial, as established in a recently signed Cooperative Research and Development Agreement (CRADA)

San Carlos, Calif., May 20, 2024 (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 first patient has been dosed in a Phase 1 clinical trial evaluating the safety and tolerability of its anti-CTLA-4 oncology drug, GIGA-564, for the treatment of metastatic or locally advanced solid tumors.

“The initiation of this Phase 1 trial with GIGA-564 marks a significant milestone as it is GigaGen’s first oncology asset to enter the clinic,” said Carter Keller, senior vice president of Grifols and head of GigaGen. “We look forward to potentially translating the superior anti-tumor performance and reduced immune-related toxicity observed with GIGA-564 in pre-clinical studies into the clinical setting. There is a pressing need for innovative therapies for solid tumors and we believe GIGA-564 has the potential to improve outcomes for patients.”

The trial is being conducted by researchers at the National Cancer Institute (NCI), part of the National Institutes of Health, in close partnership with GigaGen. For more information about the trial, refer to [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT06258304) identifier: [NCT06258304](https://clinicaltrials.gov/ct2/show/study/NCT06258304). For patients interested in enrolling in this clinical trial, please call NCI’s toll-free number: 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615); visit the website: <https://trials.cancer.gov>; and/or email: NCIMO_referrals@mail.nih.gov.

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 23,000 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 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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