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GigaGen presents positive phase 1 data on non-blocking anti-CTLA-4 drug candidate GIGA-564 at AACR 2026

- ***GIGA-564 demonstrated a favorable safety profile while exhibiting early signals of anti-tumor activity in solid tumors***
- ***GIGA-564 is a differentiated anti-CTLA-4 antibody designed to enhance anti-tumor activity and mitigate immune-related toxicities associated with CTLA-4 blockade***
- ***The trial is being conducted by researchers from the National Institutes of Health (NIH)/National Cancer Institute (NCI) through a Cooperative Research and Development Agreement (CRADA)***

Barcelona, Spain, April 17, 2026 – GigaGen Inc., a biotechnology company advancing transformative antibody drugs for immune deficiencies, infectious diseases and checkpoint resistant cancers, and a subsidiary of Grifols, is presenting positive Phase 1 data on its anti-CTLA-4 drug candidate, GIGA-564, at the American Association for Cancer Research (AACR) Annual Meeting.

GIGA-564 is a non-blocking, anti-CTLA-4 monoclonal antibody designed to target CTLA-4 in a different manner than traditional CTLA-4 blocking antibodies. To date in this first in-human Phase 1 study, GIGA-564 has exhibited a positive safety and tolerability profile while demonstrating early signs of single agent anti-tumor activity in patients with metastatic or locally advanced solid tumors.

“Observing a favorable safety profile alongside preliminary anti-tumor activity in both anti-PD-1 refractory and immuno-oncology-naïve patients is particularly noteworthy at this early stage,” said James Gulley, MD, PhD, the study’s principal investigator from NIH’s NCI. “GIGA-564 has a differentiated mechanism of action, and I look forward to continuing to evaluate its potential in highly refractory cancers with high unmet clinical need.”

Carter Keller, Senior Vice President of GigaGen, added, “There is a continuing, unmet need for innovative therapies for solid tumors and this early data demonstrates that GIGA-564 has the potential to improve outcomes for patients.”

Poster Presentation Details:

Title: Preliminary data from the first-in-human Phase 1 study of GIGA-564, a non-blocking anti-CTLA-4 antibody designed to deplete intratumoral Tregs in advanced or metastatic solid tumors.
Session: PO.CT01.01
Poster number: CT114/6
Presentation Date: April 20, 2026 at 2:00 PM PST

Presenter: James Gulley, MD, PhD**,** National Cancer Institute
Location: San Diego, CA (USA)

Summary of Results as of Data Cut-Off of January 28th, 2026 (N = 26 patients received one or more doses of GIGA-564):

- GIGA-564 demonstrated a favorable safety profile, with only one dose-limiting toxicity observed.
- Dose escalation (up to 20 mg/kg every three weeks) was accomplished as planned and the maximum tolerated dose was not exceeded.
- Among the 22 patients treated whose tumor size could be evaluated:
    - Two patients exhibited partial responses as per RECIST 1.1 criteria
    - Nine additional patients had stable disease per RECIST 1.1, including two patients who met the protocol-defined criteria for minor response (>= 20% reduction in target lesions).
    - The disease control rate (PR +SD) was 50%.

The ongoing, open-label trial is being conducted by researchers at NIH/NCI, in close partnership with GigaGen. For more information about the trial, refer to clinicaltrials.gov identifier: 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 broad activation of T effector cells. This approach has been associated with heightened systemic immune-related side effects. Moreover, recent insights reveal that previous anti-CTLA-4 drugs contribute to an increased broad 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 ability to target CTLA-4 without blocking CTLA-4 binding to its ligands, allowing it to selectively deplete Tregs in the tumor microenvironment and enhance local cancer-killing activity within the tumor. This mechanism demonstrated increased anti-tumor efficacy while limiting drug toxicities pre-clinically.

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 focuses on treating conditions centered on six core therapeutic areas: immunology, neurology, pulmonology, hematology, hepatology and intensive care.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's most diversified with more than 400 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 25,000 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).

For more information about Grifols, please visit www.grifols.com

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