



Gracell Biotechnologies Wins Overall Immunology Solution of the Year by BioTech Breakthrough Awards Program

Third annual BioTech Breakthrough Award recognizes excellence in life science and biotechnology solutions, services and companies

GC012F, a FasTCAR-enabled autologous CAR-T cell therapy, is currently being evaluated in clinical studies in multiple hematological cancers as well as autoimmune disease

SAN DIEGO and SUZHOU, China and SHANGHAI, China, Nov. 08, 2023 (GLOBE NEWSWIRE) -- Gracell Biotechnologies Inc. ("Gracell" or the "Company", NASDAQ: GRCL), a global clinical-stage biopharmaceutical company dedicated to developing innovative and highly efficacious cell therapies for the treatment of cancer and autoimmune disease, today announced that Gracell's FasTCAR-T GC012F was selected as the winner of BioTech Breakthrough's [Overall Immunology Solution of the Year](#) award.

Since its founding, Gracell has been developing a rich pipeline of transformational CAR-T therapies, aiming to broaden the use of breakthrough cell therapies across hematological malignancies, solid tumors and autoimmune conditions. GC012F, developed with Gracell's revolutionary [next-day](#) autologous CAR-T cell manufacturing platform, FasTCAR, is a CAR-T therapy candidate that stands to transform cancer and autoimmune treatment. In recently announced data from an ongoing Phase 1 investigator-initiated trial (IIT), GC012F demonstrated a 100% overall response rate and a 95% MRD- sCR rate among 22 transplant-eligible, high-risk patients with newly diagnosed multiple myeloma (NDMM). Additional positive data has recently been announced from studies evaluating GC012F for the treatment of relapsed/refractory multiple myeloma (rrMM) and B-cell non-Hodgkin's lymphoma (B-NHL). An IIT has also been launched to evaluate GC012F for the treatment of refractory systemic lupus erythematosus (rSLE) in the second quarter of this year.

In 2022, FasTCAR was named the winner of the Biotech Innovation category of the 2022 Fierce Life Sciences Innovation Award for its potential to address major industry obstacles.

"Over the last decade, the field of immunotherapy has seen rapid progress and promising results," said Dr. William (Wei) Cao, Gracell's Chief Executive Officer. "CAR-T cell therapies has been transforming the treatment paradigm for hematologic malignancies, and are showing emerging but compelling potential in autoimmune indications. At the same time, challenges have arisen around patient access and manufacturing time. Gracell is dedicated to ameliorating both these issues through GC012F and FasTCAR. With strong data reported in multiple myeloma and B-cell non-Hodgkin's lymphoma, and ongoing efforts to expand to treating autoimmune conditions, we're proud to be recognized for our innovative approach, and look forward to bringing our treatments to patients."

The BioTech Breakthrough Awards program was founded in 2021 by BioTech Breakthrough, a leading independent market intelligence organization that evaluates and recognizes standout life sciences and biotechnology companies, products and services around the globe. The mission of this annual award program is to perform the most comprehensive evaluation of life sciences and biotechnology tools, services and companies in the industry, with thousands of nominations coming in from the best and brightest biotechnology innovators around the world.

About BioTech Breakthrough

Part of [Tech Breakthrough](#), a leading market intelligence and recognition platform for global technology innovation and leadership, the BioTech Breakthrough Awards program is devoted to honoring excellence in life science and biotechnology solutions, services and companies. The BioTech Breakthrough Awards provide public recognition for the achievements of biotechnology companies and products in categories including BioPharma, Genomics, Therapeutics, Food Science and BioAgriculture, and more. For more information visit [BioTechBreakthroughawards.com](#)

About GC012F

GC012F is Gracell's FasTCAR-enabled BCMA/CD19 dual-targeting autologous CAR-T cell therapy, which aims to transform cancer and autoimmune disease treatment by driving fast, deep and durable responses with an improved safety profile. GC012F is currently being evaluated in clinical studies in multiple hematological cancers as well as autoimmune diseases, and has demonstrated a consistently strong efficacy and safety profile. Gracell has initiated a Phase 1b/2 trial evaluating GC012F for the treatment of relapsed/refractory multiple myeloma in the United States and a Phase 1/2 clinical trial in China is to be commenced imminently. An IIT has also been launched to evaluate GC012F for the treatment of rSLE.

About FasTCAR

Introduced in 2017, FasTCAR is Gracell's revolutionary next-day autologous CAR-T cell manufacturing platform. FasTCAR is designed to

lead the next generation of therapy for cancer and autoimmune diseases, and improve outcomes for patients by enhancing effect, reducing costs, and enabling more patients to access critical CAR-T treatment. FasTCAR drastically shortens cell production from weeks to overnight, potentially reducing patient wait times and probability for their disease to progress. Furthermore, FasTCAR T-cells appear younger than traditional CAR-T cells, making them more proliferative and effective at killing cancer cells. In November 2022, FasTCAR was named the winner of the Biotech Innovation category of the 2022 Fierce Life Sciences Innovation Awards for its ability to address major industry obstacles.

About Gracell

Gracell Biotechnologies Inc. ("Gracell") is a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies for the treatment of cancers and autoimmune diseases. Leveraging its innovative FasTCAR and TruUCAR technology platforms and SMART CART™ technology module, Gracell is developing a rich clinical-stage pipeline of multiple autologous and allogeneic product candidates with the potential to overcome major industry challenges that persist with conventional CAR-T therapies, including lengthy manufacturing time, suboptimal cell quality, high therapy cost, and lack of effective CAR-T therapies for solid tumors and autoimmune diseases. The lead candidate BCMA/CD19 dual-targeting FasTCAR-T GC012F is currently being evaluated in clinical studies for the treatment of multiple myeloma, B-NHL and systemic lupus erythematosus (SLE). For more information on Gracell, please visit www.gracellbio.com. Follow @GracellBio on [LinkedIn](#).

Cautionary Noted Regarding Forward-Looking Statements

Statements in this press release about future expectations, plans, and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "look forward to," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including factors discussed in the section entitled "Risk Factors" in Gracell's most recent annual report on Form 20-F, as well as discussions of potential risks, uncertainties, and other important factors in Gracell's subsequent filings with the U.S. Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof. Gracell specifically disclaims any obligation to update any forward-looking statement, whether due to new information, future events, or otherwise. Readers should not rely upon the information on this page as current or accurate after its publication date.

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