



Gracell Biotechnologies to Present Updated Results from BCMA/CD19 Dual-Targeting FasTCAR-T GC012F in Newly Diagnosed Multiple Myeloma at the 65th American Society of Hematology Annual Meeting & Exposition

Oral presentation of the updated results from ongoing Phase 1 investigator-initiated study of GC012F in frontline setting for transplant-eligible, high-risk newly diagnosed multiple myeloma

GC012F is a FasTCAR-enabled B-cell maturation antigen (BCMA) and CD19 dual-targeting autologous cell therapy being evaluated for hematologic malignancies and autoimmune disease

SAN DIEGO and SUZHOU, China and SHANGHAI, China, Nov. 02, 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 the updated results from its clinical investigator-initiated trial (IIT) of GC012F for treatment of newly diagnosed multiple myeloma (NDMM) will be presented as an oral presentation at the 65th American Society of Hematology (ASH) Annual Meeting & Exposition taking place in San Diego, California and online during December 9-12, 2023.

The ongoing Phase 1 IIT (NCT04935580) in China is evaluating the safety and efficacy of GC012F, a FasTCAR-enabled autologous BCMA and CD19 dual-targeted CAR-T cell therapy, in the frontline setting for transplant-eligible, high risk NDMM patients. The first results from this study on 13 initial patients were presented at the ASH Annual Meeting in 2022. Updated results, including longer-term follow-up and data from additional patients in the study, will be shared at this year's ASH conference.

"We are pleased to present updated results from the Phase 1 IIT study of GC012F in NDMM. During last year's ASH meeting, we unveiled the first results for the initial 13 patients, marking a pioneering moment for CAR-T clinical data within the frontline setting," said Dr. Wendy Li, Gracell's Chief Medical Officer. "With additional patients enrolled and longer follow-up, we are encouraged to report that FasTCAR-T GC012F has continued to demonstrate impressive depth of responses and a highly favorable safety profile. We firmly believe that GC012F represents a next generation CAR-T therapy that has the potential to revolutionize the treatment landscape for multiple myeloma patients in front- and early-line settings."

Oral presentation details are as follows:

- **Presentation title:** Updated Results of a Phase I Open-Label Single-Arm Study of Dual Targeting BCMA and CD19 FasTCAR-T Cells (GC012F) As First-Line Therapy for Transplant-Eligible Newly Diagnosed High-Risk Multiple Myeloma
- **Abstract number:** 1022
- **Presentation category:** 704. Cellular Immunotherapies: Early Phase and Investigational Therapies
- **Presentation time:** Monday, December 11, 2023, 4:45 PM PT
- **Presentation location:** Room 6A, San Diego Convention Center

Additional information about Gracell's oral presentation at ASH will be available on the ASH conference [website](#) at 9 a.m. ET today.

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 refractory systemic lupus erythematosus (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.

Media Contacts Marvin Tang marvin.tang@gracellbio.com Jessica Laub jessica.laub@westwicke.com Investor Contacts Gracie Tong gracie.tong@gracellbio.com Stephanie Carrington stephanie.carrington@westwicke.com