PRESS RELEASE

Gracell Biotechnologies Presents Updated Clinical Data from FasTCAR-T GC012F Demonstrating Deep and Durable Responses in Newly Diagnosed Multiple Myeloma at ASH 2023

Minimal residual disease negativity (MRD-) observed in all treated patients in the ongoing study, with 95% (21/22) achieving stringent complete response (sCR) through a median follow-up of 18.8 months

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

SAN DIEGO and SUZHOU, China and SHANGHAI, China, Dec. 11, 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 presented updated results from the clinical investigator-initiated trial (IIT) of GC012F for treatment of newly diagnosed multiple myeloma (NDMM) as an oral presentation at the 65th American Society of Hematology (ASH) Annual Meeting & Exposition taking place in San Diego, California and online.

GC012F demonstrated a 100% overall response rate (ORR) and 95% MRD- sCR rate among 22 transplant-eligible, high-risk NDMM patients as of the data cutoff date of October 1, 2023. The data included longer-term follow-up from the initial 16 patients, for whom earlier results were presented at the 2022 American Society for Hematology (ASH) Annual Meeting, plus six additional patients that were enrolled and treated later. The data also showed that GC012F was well-tolerated with no new safety signals observed in this frontline application of CAR-T therapy.

"We are delighted to announce the updated data of FasTCAR-T GC012F for the treatment of multiple myeloma patients in the frontline setting. The clinical data continue to highlight the depth of response and highly favorable safety profile delivered by GC012F, as well as the greatly shortened manufacturing turnaround time, demonstrating the compelling benefits of our innovative dual-targeting approach and the FasTCAR next-day manufacturing technology," said Dr. Wendy Li, Gracell's Chief Medical Officer. "This dataset further strengthens the growing clinical evidence supporting the considerable potential of FasTCAR-T GC012F and underscores our dedication to pioneering breakthroughs in cell therapy."

In the ongoing single-arm, open label, Phase 1 IIT, patients with NDMM were enrolled and treated with GC012F at three dose levels. All patients had one or more high-risk features, of which 91% (20/22) were classified as Stage II or III based on the Revised International Staging System (R-ISS), and 55% (12/22) had extramedullary plasmacytoma.

As of the data cutoff date of October 1, 2023 and with a median follow-up of 18.8 months (range: 6.6-28.4 months), the 22 evaluable patients achieved strong response rates following GC012F infusion:

- 100% (22/22) ORR;
- 95% (21/22) sCR;
- 100% (22/22) MRD-, as assessed by Euroflow at a sensitivity of 10^{-6};
- Median duration of response (DOR) and median progression free survival (PFS) were not reached at the data cutoff date.

GC012F continued to show a favorable safety profile in the longer-term follow-up with no new safety findings:

- Only 27% (6/22) patients experienced cytokine release syndrome (CRS), all of which were low-grade, either Grade 1 (23%, 5/22) or Grade 2 (5%, 1/22) and resolved within four days;
- No CRS of any grade occurred in the remaining 73% (16/22) of patients;
- No immune effector cell-associated toxicity (ICANS) or neurotoxicity of any grade occurred.

Additional information about the presentation and the ASH Annual Meeting is available on the ASH website.

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 or 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) and Investigational New Drug application to study GC012F in rSLE has been cleared by the U.S. FDA.

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 2022 and 2023, FasTCAR was named the winner of the Biotech Innovation category of the 2022 Fierce Life Sciences Innovation Awards and the Overall Immunology Solution of 2023 by BioTech Breakthrough 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 SLE. For more information on Gracell, please visit www.gracellbio.com. Follow @GracellBio on LinkedIn.

Cautionary Notes 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