PRESS RELEASE

Gracell Biotechnologies Reports Updated Clinical Data for FasTCAR-T GC012F for High-Risk, Newly Diagnosed Multiple Myeloma, Demonstrating 100% Stringent Complete Response Rate

- *Updated results from the BCMA/CD19 dual-targeted GC012F, including longer-term follow-up and three additional patients, presented at the International Myeloma Society Annual Meeting*

- *100% (19/19) patients achieved minimal residual disease negative stringent complete response (MRD- sCR)*

SAN DIEGO and SUZHOU, China and SHANGHAI, China, Sept. 27, 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 longer-term follow-up data from an ongoing Phase 1 investigator-initiated trial (IIT) evaluating GC012F, a CD19 and B-cell maturation antigen (BCMA) dual-targeted autologous CAR-T therapeutic candidate, as a frontline treatment for patients with transplant-eligible, high-risk, newly diagnosed multiple myeloma (NDMM). The abstract (P-136) was presented as a poster at the 20th International Myeloma Society (IMS) Annual Meeting in Athens, Greece.

GC012F demonstrated a 100% overall response rate (ORR) and a 100% MRD- sCR rate among 19 transplant-eligible, high-risk NDMM patients as of the data cutoff date of August 1, 2023. The data include longer-term follow-up from the initial 16 patients, for whom early results were presented at the 2022 American Society for Hematology (ASH) Annual Meeting, plus three additional patients enrolled and treated. The data also showed that GC012F was well-tolerated with no new safety signals observed in this frontline application of CAR-T therapy.

"Patients with high-risk NDMM, including those who are transplant-eligible, typically face suboptimal outcomes with the current standard of care. Innovation is imperative to address the challenges faced by this group of hard-to-treat patients," said Dr. Wendy Li, Chief Medical Officer at Gracell. "MRD- sCR is the deepest response possible in the treatment of multiple myeloma patients. We are delighted to report that in this study, all 19 NDMM patients treated by GC012F achieved MRD- sCR with favorable safety. This stands as a testament to the tremendous potential of CAR-T therapy, our pioneering BCMA/CD19 dual-targeting approach, and the enhanced T cell fitness enabled by FasTCAR manufacturing technology."

In the ongoing single-arm, open label, Phase 1 IIT, patients with NDMM were enrolled and treated with GC012F at three target dose levels. All patients had one or more high-risk features, of which 89% were classified as Stage II or III based on the Revised International Staging System (R-ISS) and 63% had extramedullary plasmacytoma.

As of the data cutoff date of August 1, 2023, with a median follow-up of 15.3 months (range: 3.1-24.5 months), the 19 evaluable patients achieved strong response rates following GC012F infusion:

- 100% (19/19) ORR;
- 100% (19/19) sCR;
- 100% (19/19) of patients achieved minimal residual disease (MRD) negativity, assessed by Euroflow with the sensitivity of 10^{-6};
- Median duration of response (DOR) was not reached.

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

- Only low-grade cytokine release syndrome (CRS) was reported; among the six patients with Grade 1 or 2 CRS, most cases were Grade 1 (5/19, 26%) with only one case of Grade 2 (1/19, 5%);
- No CRS of any grade occurred in the remaining 68% (13/19) of patients;
- No immune effector cell-associated toxicity (ICANS) of any grade occurred.

Additional information about the poster and the IMS Annual Meeting is available on the IMS 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 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. Gracell has also launched an IIT evaluating GC012F for the treatment of refractory systemic lupus erythematosus (rSLE).

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 CAR™ 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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