PRESS RELEASE

Gracell Biotechnologies to Present Updated Clinical Data on BCMA/CD19 Dual-Targeting CAR-T GC012F for Relapsed/Refractory Multiple Myeloma at 2022 ASCO Annual Meeting

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China, May 26, 2022 /PRNewswire/ -- Gracell Biotechnologies Inc. ("Gracell" or the "Company", NASDAQ: GRCL), a global clinical-stage biopharmaceutical company dedicated to developing highly efficacious and affordable cell therapies for the treatment of cancer, today announced that it will present updated clinical data from a multicenter investigator-initiated trial (IIT) evaluating GC012F, the company's B-cell maturation antigen (BCMA) and CD19 dual-targeting CAR-T candidate, for the treatment of relapsed/refractory multiple myeloma (RRMM) in an oral abstract presentation at the 2022 American Society of Clinical Oncology (ASCO 2022) Annual Meeting.

GC012F is an autologous CAR-T therapeutic candidate dual-targeting BCMA and CD19, developed using Gracell's proprietary FasTCAR platform, which enables next-day manufacturing of CAR-T therapies. In November 2021, GC012F was granted Orphan Drug Designation for the treatment of multiple myeloma (MM) by the U.S. Food and Drug Administration. GC012F is currently being evaluated in IITs in China including in MM and B-NHL.

"We are thrilled to present updated data from our ongoing study of GC012F for the treatment of patients with RRMM at the oral abstract session at ASCO," said Dr. Martina A. Sersch, Chief Medical Officer of Gracell. "GC012F is the first dual-targeting CAR-T with clinical data in RRMM, which is designed to improve depth of response as well as tackling some of the major challenges of CAR-T therapy, including the need for faster delivery to the patients in need . We have followed patients for over two and a half years and also enrolled new patients into the study. RRMM still remains an area of unmet medical need, including the need of deepening responses for eligible patients."

From October 2019 to November 2021, 28 heavily pretreated RRMM patients were enrolled and treated in this single-arm, open label, multicenter IIT with a single infusion of GC012F at three dose levels: $1x10^5$ cells/kg (DL1), $2x10^5$ cells/kg (DL2), and $3x10^5$ cells/kg (DL3). An additional 9 patients were treated in three different dose levels since the last update reported at ASCO and EHA in 2021. 89.3% (25/28) patients were high risk based on mSMART 3.0 criteria and patients had received a median of five prior lines of therapy.

At the data cutoff of January 26, 2022, the 28 patients had been evaluated for response with a median follow-up time of 6.3 months, ranging from 1.8 to 29.9 months. Patients are continued to be followed for deepening responses. The response rate at different dose levels was 100% (2/2) in DL1, 80% (8/10) in DL2, and 93.8% (15/16) in DL3. All (27/27, 100%) MRD-assessable patients achieved minimal residual disease (MRD) negativity. 75% (21/28) of all patients treated achieved MRD- sCR.

The safety profile of GC012F was consistent with previous findings with mostly low grade of cytokine release syndrome (CRS) (Grade 0-2 (93%)). No Grade 4 or 5 CRS, or any Grade immune effector cell-associated neurotoxicity syndrome (ICANS) were observed. Patients continue to be monitored for safety and efficacy including best overall response and duration of response.

Gracell will also present as an oral abstract presentation the updated results from this IIT evaluating GC012F for the treatment of RRMM patients at the European Hematology Association 2022 Hybrid Congress. For more information on the study, please visit ClinicalTrials.gov using the identifier: NCT04236011.

Details of the ASCO presentation follow below:

2022 ASCO Annual Meeting

- **Abstract title:** Updated results of a multicenter first-in-human study of BCMA/CD19 dual-targeting FasTCAR-T GC012F for patients with relapsed/refractory multiple myeloma (RRMM)
- **Abstract number:** 8005
- **Session title:** Hematologic Malignancies – Plasma Cell Dyscrasia
- **Presentation time:** Sunday, June 5 at 9:36 AM CT
- **Presentation location:** S406

About GC012F

GC012F is a FasTCAR-enabled dual-targeting CAR-T product candidate that is currently being evaluated in IIT studies in China for the treatment of multiple myeloma and B-cell non-Hodgkin's lymphoma. GC012F simultaneously targets CD19 and BCMA to drive fast, deep and durable responses, which can potentially improve efficacy and reduce relapse in multiple myeloma and B-NHL patients.

About FasTCAR

CAR-T cells manufactured on Gracell's proprietary FasTCAR platform appear younger, less exhausted and show enhanced proliferation, persistence, bone marrow migration and tumor cell clearance activities as demonstrated in preclinical studies. With next-day manufacturing, FasTCAR is able to significantly improve cell production efficiency which may result in meaningful cost savings, and, together with fast turnaround time, enables enhanced accessibility of cell therapies for cancer patients.

About Gracell

Gracell Biotechnologies Inc. ("Gracell") is a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies. Leveraging its pioneering FasTCAR and TruUCAR technology platforms and SMART CAR^{TM} 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. 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. These statements include, but are not limited to, statements relating to the expected trading commencement and closing date of the offering. The words "anticipate," "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 Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Gracell specifically disclaims any obligation to update any forward-looking statement, whether as a result of 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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