



Gracell Biotechnologies to Present Updated Clinical Data on BCMA/CD19 Dual-Targeting FasTCAR-T GC012F at 2023 ASCO Annual Meeting

SAN DIEGO, Calif., and SUZHOU and SHANGHAI, China, April 26, 2023 /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 on GC012F, the Company's FasTCAR-enabled autologous CAR-T cell therapy dual-targeting B-cell maturation antigen (BCMA) and CD19, from ongoing investigator-initiated trials (IIT) in relapsed-refractory multiple myeloma (RRMM) and B-cell non-Hodgkin's lymphoma (B-NHL) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, being held June 2-6, 2023, in Chicago and online.



"We are looking forward to sharing updated results from our ongoing studies evaluating GC012F in relapsed/refractory multiple myeloma and B-cell non-Hodgkin's lymphoma. We are particularly encouraged by the recognition of our long-term follow-up data of GC012F in RRMM, which will be presented at an oral session. We believe for these hematological cancers, there is critical need for transformational treatment options with strong efficacy, favorable safety profiles and rapid manufacturing," said Dr. Wendy Li, Gracell's Chief Medical Officer. "With plans to commence clinical trials in the U.S. and China following the receipt of regulatory clearance of Investigational New Drug applications, 2023 is a critical year for both GC012F and Gracell. We plan to showcase the latest data to our peers in cancer research at the ASCO Annual Meeting that augments the clinical validation of the FasTCAR platform in a wide array of indications, emphasizing the importance of the dual-targeted approach and the potential benefits of enhanced T cell quality and accelerated delivery of the therapy to patients thanks to Gracell's FasTCAR next-day manufacturing technology."

BCMA/CD19 Dual-Targeting FasTCAR-T GC012F for the Treatment of RRMM

Longer-term follow-up data from a multicenter investigator-initiated trial evaluating GC012F for the treatment of RRMM in heavily pretreated patients will be presented as an [oral abstract session](#).

Oral presentation details are as follows:

- **Abstract title:** Updated results of a phase I, open-label study of BCMA/CD19 dual-targeting fast CAR-T GC012F for patients with relapsed/refractory multiple myeloma (RRMM)
- **Abstract number:** 8005
- **Session title:** Hematologic Malignancies – Plasma Cell Dyscrasia
- **Session type:** Oral Abstract Session
- **Presentation time:** Saturday, June 3 at 1:15 PM – 4:15 PM CDT

BCMA/CD19 Dual-Targeting FasTCAR-T GC012F for the Treatment of B-NHL

A separate [poster presentation](#) will highlight updated clinical results from an ongoing IIT evaluating GC012F for the treatment of relapsed/refractory B-NHL. While CD19-directed CAR-T has proven effective for the treatment of NHL^{[1],[2]}, the CD19/BCMA dual-targeting approach is novel for this indication. Additionally, this study further validates the FasTCAR platform.

Poster presentation details are as follows:

Abstract title: Updated clinical results of first-in-human study of CD19/BCMA dual-targeting fast CAR-T GC012F for patients with relapsed/refractory B-cell non-Hodgkin's lymphoma

- **Abstract number:** 7562
- **Session title:** Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
- **Session type:** Poster Abstract Session
- **Session date & time:** Monday, June 5 at 8:00 – 11:00 AM CDT

Full abstracts will be released on May 25, 2023 at 5 PM EDT. Additional information about the presentation and the ASCO Annual Meeting is available on the [ASCO website](#).

About GC012F

GC012F is Gracell's FasTCAR-enabled BCMA/CD19 dual-targeting autologous CAR-T cell therapy, which aims to transform cancer treatment by driving fast, deep and durable responses with improved safety profile. GC102F is currently being evaluated in investigator-initiated trials in multiple myeloma and B-cell non-Hodgkin's lymphoma (B-NHL), and has demonstrated a consistently strong efficacy and safety profile. In February 2023, Gracell announced regulatory clearance of Investigational New Drug applications in the U.S. and China to commence clinical trials evaluating GC012F for the treatment of relapsed/refractory multiple myeloma.

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 cancer therapy and improve outcomes for patients by enhancing efficacy, 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 and are more robust 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 and gene therapies. Leveraging its pioneering 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. 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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[1] American journal of hematology. 2021; 96(10):1295-1312.

[11] Lancet Oncol. 2019;20(1):31-42.

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