



Gracell Biotechnologies to Present Clinical Data on BCMA/CD19 Dual-Targeting FasTCAR-T GC012F in RRMM and B-NHL and Donor-Derived CAR-T GC007g in B-ALL at EHA2023 Congress

First disclosure of data from Phase 1 study of the donor-derived allogeneic CAR-T GC007g shows 100% overall response rate (ORR) and a favorable safety profile for treatment of relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL)

Longer-term GC012F data in relapsed/refractory multiple myeloma (RRMM) and B-cell non-Hodgkin's lymphoma (B-NHL) indications to be highlighted, with B-NHL data selected for oral presentation

SAN DIEGO, Calif., and SUZHOU and SHANGHAI, China, May 11, 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 clinical data from three studies in B-NHL, RRMM and B-ALL will be presented at the 2023 European Hematology Association (EHA) Annual Meeting taking place June 8-15 in Frankfurt, Germany, and online. Clinical data from GC012F, the Company's FasTCAR-enabled autologous CAR-T cell therapy dual-targeting B-cell maturation antigen (BCMA) and CD19, in B-NHL (which was selected as an oral presentation) and RRMM, will also be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, and are currently under embargo until Thursday, May 25.



A third abstract highlights first clinical data from a Phase 1 trial evaluating GC007g, a CD19-targeted donor-derived allogeneic CAR-T cell therapy, in patients with r/r B-ALL who relapsed after receiving allogeneic stem cell transplant (allo-HSCT). The data showcases a 100% ORR and will be presented on Friday, June 9, 6:00 – 7:00 PM CEST.

"We are pleased to have our FasTCAR-T GC012F data in B-NHL selected for an oral presentation, and look forward to presenting additional data in the RRMM indication, as well as from our donor-derived CAR-T candidate for r/r B-ALL, at this year's EHA Congress, demonstrating the breadth of Gracell's innovation in CAR-T cell therapy across technology platforms and indications," said Dr. Wendy Li, Gracell's Chief Medical Officer. "The donor-derived CAR-T candidate GC007g represents a unique allogeneic approach for a group of r/r B-ALL patients that could not benefit from autologous CAR-T. We are excited to share the first data from the Phase 1 trial evaluating GC007g in this challenging set of patients and to demonstrate encouraging persistence of allogeneic CAR-T cells, durable remission, and a favorable safety profile."

CD19-Targeted Donor-Derived Allogeneic GC007g for the Treatment of r/r B-ALL

GC007g is a donor-derived CAR-T candidate that has been designed for r/r B-ALL patients who may not be eligible for autologous CAR-T therapy due to poor cell fitness, infections, and other unsuitable conditions.

Between March 2021 and May 2022, nine r/r B-ALL patients were enrolled and treated in the Phase 1 portion of the registrational Phase 1/2 clinical trial in China evaluating GC007g at two different dose levels. All patients had relapsed B-ALL following a partially or fully matched prior allo-HSCT. Six patients relapsed after haploidentical HSCT, while three patients relapsed post matched sibling donors HSCT. Three patients had received a GC007g infusion at dose level 1 (DL1) 6×10^5 cells/kg and six patients had received an infusion at dose level 2 (DL2) 2×10^6 cells/kg. Donor-derived CAR T-cells were successfully manufactured for all patients, with a median time from leukapheresis to infusion of 33 days (range 30-74 days).

At day 28 after infusion, 100% patients achieved minimal residual disease negative complete remission with/without incomplete count recovery (MRD- CR/CRi). At a median follow-up of 445 days (range 218-649 days), seven of nine patients remained in CR/CRi, while

two patients had CD19 negative relapse. The ORR was 100% (7/7), 85.7% (6/7) and 50% (2/4) at month 3, 6, and 12, respectively. The 1-year progression-free survival (PFS) and overall survival (OS) were 76.2% and 85.7%, respectively.

Cytokine release syndrome (CRS) is presented as Grade 1 to Grade 3 events, with no Grade 4 or 5 events, and all resolved after treatment. No immune effector cell-associated neurotoxicity syndrome (ICANS) was observed. Three patients were observed to have acute graft-versus-host disease (aGvHD) and all cases resolved after standard-of-care treatment. No chronic graft-versus-host disease (cGvHD) occurred.

The Phase 2 clinical trial of GC007g is currently recruiting patients in China.

Results will be detailed in a poster presentation, which will be available to registered attendees on the EHA website.

Details of Gracell's GC007g [poster presentation](#) are as follows:

- **Abstract title:** Donor-Derived Anti-CD19 Chimeric Antigen Receptor T Cells for B-Cell Acute Lymphoblastic Leukemia: A Phase 1 Trial
- **Abstract code:** P369
- **Session title:** Poster session
- **Presentation time:** Friday, June 9, 6:00 – 7:00 PM CEST

Additional Presentations for BCMA/CD19 Dual-Targeting FasTCAR-T GC012F for the Treatment of B-NHL and RRMM

Gracell will also present updated results from two studies evaluating its investigational BCMA/CD19 dual-targeting FasTCAR-T GC012F candidate in B-NHL (as an oral abstract) and in RRMM (as a poster). These data are currently under embargo and will publish on Thursday, May 25, concurrently with ASCO.

Details of the GC012F [oral presentation](#) in B-NHL are as follows:

- **Abstract title:** Updated clinical results of first-in-human study of CD19/BCMA dual-targeting FasTCAR-T GC012F for patients with relapsed/refractory B-cell non-Hodgkin's lymphoma (B-NHL)
- **Abstract code:** S234
- **Session title:** S432 Aggressive lymphoma - CAR-T
- **Session location:** Festhalle
- **Presentation time:** Saturday, June 10, 4:30 – 5:45 PM CEST

Details of the GC012F [poster presentation](#) in RRMM are as follows:

- **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 code:** P869
- **Session title:** Poster session
- **Presentation time:** Friday, June 9, 6:00 – 7:00 PM CEST

For more information about the EHA2023 Congress, visit www.ehaweb.org.

About GC007g

GC007g is an allogeneic CD19-targeted CAR-T cell therapy, derived from HLA-matched donors, under development for the treatment of r/r B-ALL patients who failed transplant and may not be suitable for autologous CAR-T therapy.

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. GC012F 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 enhanced 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 B-ALL

Acute lymphoblastic leukemia (ALL) is a type of blood cancer characterized by proliferation of immature lymphocytes in the bone marrow, which can involve either T lymphocytes (T-ALL), or B lymphocytes (B-ALL). Globally, approximately 64,000 patients are diagnosed with ALL every year with an estimated 6,540 new cases to be diagnosed in the United States in 2023.[1] B-ALL accounts for 75% of ALL diagnoses in adults.

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](https://www.linkedin.com/company/gracell-biotechnologies).

[1] Data source: American Cancer Society

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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