
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of June 2022

Commission file number: 001-39838

Gracell Biotechnologies Inc.

**Building 12, Block B, Phase II
Biobay Industrial Park
218 Sangtian St.
Suzhou Industrial Park, 215123
People's Republic of China
(Address of Principal Executive Offices)**

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F. Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Gracell Biotechnologies Inc.

By: /s/ Yili Kevin Xie

Name: Yili Kevin Xie

Title: Chief Financial Officer

Date: June 14, 2022

PRESS RELEASE



Gracell Biotechnologies Presents Updated Clinical Data for BCMA/CD19 Dual-targeting FasTCAR GC012F in RRMM at EHA2022 Congress, Highlighting 100% MRD Negativity Rate in All Treated Patients

Gracell also presented data on GC012F for treatment of B-NHL and allogeneic TruUCAR-candidate GC502 for treatment of B-ALL

Management to host clinical update call on Monday, June 13, at 8:00AM ET

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China (June 12, 2022) – 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 the updated clinical data from a multicenter study evaluating GC012F, the Company’s autologous CAR-T therapeutic candidate dual-targeting B-cell maturation antigen (BCMA) and CD19, for the treatment of relapsed/refractory multiple myeloma (RRMM). Gracell shared the data at the European Hematology Association 2022 Hybrid Congress (EHA2022 Congress), held from June 9-12 in Vienna, Austria.

“The updated data of the final dataset of 29 treated patients underscore the deep responses achieved with GC012F, including a 100% MRD negativity rate in all patients treated,” commented Dr. Martina Sersch, Chief Medical Officer of Gracell. “GC012F for the treatment of RRMM continues to demonstrate a favorable safety profile and a promising mDOR of 15.7 months in mostly high risk, heavily pretreated patients, including those with extramedullary disease and those who were previously exposed to PI, IMiDs and anti-CD38 agents. In addition, we presented at EHA the first-in-human data of GC012F in B-NHL, a potential second indication. We look forward to continuing developing this lead asset and providing a new treatment option to the patients with high unmet needs.”

Additionally, on June 10, Gracell presented the first clinical results of the first-in-human phase 1 investigator-initiated study (IIT) in China evaluating the safety and tolerability of GC012F in B-cell non-Hodgkin’s lymphoma patients, and longer-term follow-up results of a safety and efficacy study from an IIT evaluating allogeneic TruUCAR-T GC502 in patients with B-cell acute lymphoblastic leukemia. Gracell announced these data in a [press release](#) on May 12.

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

From October 2019 to January 2022, 29 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: 1x10⁵ cells/kg (DL1), 2x10⁵ cells/kg (DL2), and 3x10⁵ cells/kg (DL3). 90% (26/29) 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 June 8, 2022, the 29 patients had been evaluated for response with a median follow-up duration of 11 months, ranging from 4.9 to 34.5 months. Patients continue 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 100% (17/17) in DL3. All patients 100% (29/29) achieved minimal residual disease (MRD) negativity. 75.9% (22/29) of all patients treated achieved MRD- sCR. Median duration of response (DOR) at data cut off was 15.7 months (95% CI: 7.6-33.1).

The safety profile of GC012F was consistent with previous findings with mostly low grade of cytokine release syndrome (CRS). 93% (27/29) of events were Grade 0-2 and 7% (2/29) of events were Grade 3. 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 (BOR) and DOR. Due to the COVID-19 related lockdowns at the lead site of the study in Shanghai, China, follow-up assessment visits of certain patients were delayed and Gracell is looking forward to providing further updates in future publications for DOR, ORR, and BOR in all treated patients.

In November 2021, GC012F was granted Orphan Drug Designation for the treatment of multiple myeloma by the U.S. Food and Drug Administration.

Details of the presentation 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)
- **Session title:** Relapsed/refractory myeloma: BCMA-directed therapies
- **Presentation time:** Sunday, June 12 from 11:30 AM – 12:45 PM CEST
- **Presentation location:** Hall A2-A3

For more information about the EHA2022 Hybrid Congress, visit www.ehaweb.org.

Clinical update conference call and webcast details

Monday, June 13, 2022 @ 8:00AM ET

Investor domestic dial-in: (833) 693-0545

Investor international dial-in: +1(661) 407-1586

Conference ID: 1820109

Live webcast link: <https://ir.gracellbio.com/news-events/events-and-presentations>

A replay of the webcast will be available on ir.gracellbio.com shortly after the conclusion of the event for 90 days.

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 release 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™ 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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