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 May 2021

Commission file number: 001-39838

Gracell Biotechnologies Inc.

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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

Exhibit No.	Description
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: May 21, 2021

PRESS RELEASE

Gracell Biotechnologies to Present Updated Results of GC012F FasTCAR-enabled BCMA/CD19 Dual-targeting CAR-T Cell Therapy for Relapsed/Refractory Multiple Myeloma at ASCO 2021 and EHA 2021

SUZHOU, China and Palo Alto, California, May 19, 2021 — Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell"), a global clinical-stage biopharmaceutical company dedicated to developing highly efficacious and affordable cell therapies for the treatment of cancer, is presenting updated results of their first-in-human multicenter study of GC012F for the treatment of relapsed and/or refractory multiple myeloma, a FasTCAR-enabled BCMA/CD19 dual-targeting CAR-T cell therapy currently in development for the treatment of multiple myeloma, at the 2021 American Society of Clinical Oncology ("ASCO") Annual Meeting and the European Hematology Association 2021 ("EHA2021") Congress.

GC012F is a BCMA/CD19 dual-targeting CAR-T cell therapy developed on Gracell's proprietary FasTCAR next-day manufacturing technology platform and is being evaluated in a Phase 1 investigator-initiated trial study.

- As of January 12, 2021, the study had enrolled and treated 19 patients at three dose levels with the highest dose level of $3x10^5$ cells per kg. Additional patients were treated since last update (reported at ASH 2020) in the highest dose level.
- Early Overall Response Rate (ORR) shows a promising 94.7% (18/19) with all responses being VGPR or better (sCR), demonstrating fast, deep and durable responses in all dose levels.
- 100% of the patients treated at the highest dose level (n=9) obtained MRD negative sCR.
- 18 of the 19 patients (94.7%) treated were classified as high-risk according to mSMART 3.0 guidelines and patients had received a median of 5 prior lines of therapy.
- 94.7% (18/19) of the patients were triple exposed to a PI, IMiD, and at least a third treatment modality, including anti-CD38 targeted therapy.
- The safety profile of GC012F was consistent with previous findings with mostly low grade of cytokine release syndrome (CRS) (84% Grade 1/2, 11% (n=2) patients Grade 3). No Grade 4 or 5 CRS and no ICANS (immune effector cell-associated neurotoxicity) were observed in any of the 19 patients. Treatment-emergent adverse events (TEAEs) presented predominantly as cytopenias and AST increase. All TEAEs resolved with standard therapy.
- Patients are continued to be followed for efficacy and safety.

"The longer-term follow-up and additional patients treated with GC012F confirm the previous findings presented at ASH 2020 and are an additional confirmation for the impressive safety and efficacy shown with our dual-targeting CAR-T therapy, including in high risk patients," said Dr. Martina Sersch, MD, Chief Medical Officer of Gracell. "High-risk patients are difficult to treat. All patients in the highest dose level showed an initial 100% MRD negative sCR, and these deep responses were maintained at month six post-infusion after treatment with GC012F and beyond. These are very encouraging data and they hold a promise for multiple myeloma patients with high risk features and beyond, including those who have failed or are no longer responding to standard treatment options. We are planning to expand our program globally including earlier lines of therapy and are looking forward to sharing updates as we advance our programs."

Details on the poster presentations are shown below:

2021 ASCO Annual Meeting

Abstract 8014: Long-term follow-up results of a multicenter first-in-human study of the dual BCMA/CD19 targeted FasTCAR-T GC012F for patients with relapsed/refractory multiple myeloma

Poster Release Date: June 4, 2021

EHA2021 Virtual Congress

Abstract EP962: Long-term follow-up results of a multicenter first-in-human study of the dual BCMA/CD19 targeted FasTCAR-T GC012F for patients with relapsed/refractory multiple myeloma

Poster Release Date: June 11, 2021

About Multiple Myeloma

Multiple myeloma (MM) is the third most common type of blood cancer in the United States, originating from plasma cells, a type of immune cell that is typically responsible for secreting antibodies to fight infection. Globally, approximately 160,000 patients are diagnosed with MM every year with over 32,000 expected to be diagnosed in the United States in 2020. In recent years, many advances have been made to treat MM, however, the disease is still considered incurable. Multiple myeloma patients with certain cytogenetic and other abnormalities are classified by the International Myeloma Working Group, or IMWG, and Mayo Stratification for Myeloma and Risk-Adapted Therapy, or mSMART, criteria as high-risk patients. They represent 20-30% of the overall MM patient population. High-risk patients have a much higher risk of early relapse and shorter progression free and overall survival. These patients are considered the most difficult to treat MM patients, typically with a poor prognosis.

About GC012F

GC012F is a FasTCAR-enabled dual-targeting CAR-T product candidate that is currently being studied in an ongoing investigator-initiated Phase 1 trial across multiple centers in China for the treatment of MM. GC012F tackles MM by simultaneously targeting both malignant plasma cells expressing BCMA and early progenitor cells expressing CD19 in order to drive fast, deep and durable responses in MM 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, increasing the 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, 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 production 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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