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 December 2023

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

INCORPORATION BY REFERENCE

This report on Form 6-K is hereby incorporated by reference in the registration statements of Gracell on Form F-3 (No. 333-264545 and No. 333-274191) to the extent not superseded by documents or reports subsequently filed.

EXHIBITS

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/ Kevin Yili Xie
Name: Kevin Yili Xie
Title: Chief Financial Officer

Date: December 22, 2023

Exhibit 99.1

Gracell Biotechnologies Announces China NMPA Clearance for IND Application for Phase 1/2 Clinical Trial of FasTCAR-T GC012F for the Treatment of Refractory Systemic Lupus Erythematosus

Expands clinical development of GC012F in rSLE following FDA IND clearance for Phase 1/2 trial in the United States

Gracell is pioneering use of a CD19/BCMA dual-targeted CAR-T cell therapy in rSLE, aiming for deeper and wider depletion of disease-causing antibody secreting cells and B-cells

FasTCAR-T GC012F has demonstrated a favorable safety profile in clinical investigator-initiated trials in 60 patients with multiple myeloma and B-cell non-Hodgkin lymphoma

SAN DIEGO, Calif., and SUZHOU and SHANGHAI, China, December 21, 2023 -- Gracell Biotechnologies Inc. ("Gracell" or the "Company", NASDAQ: GRCL), a global clinical-stage biopharmaceutical company dedicated to developing innovative and highly efficacious cell therapies for the treatment of cancer and autoimmune disease, today announced that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has cleared Gracell's Investigational New Drug (IND) application for GC012F, an autologous CAR-T therapeutic candidate, for the treatment of refractory systemic lupus erythematosus (rSLE).

Under the IND, Gracell plans to initiate a Phase 1/2 clinical study in China to further evaluate GC012F in rSLE patients. As announced Nov. 27, the Company will also commence Phase 1/2 clinical study in the U.S.. An IIT is underway to evaluate GC012F for the treatment of rSLE.

"This milestone marks our rapid progress in advancing development of GC012F in rSLE, an autoimmune disease with high unmet need," said Dr. William Cao, founder, Chairman and Chief Executive Officer of Gracell. "With an IIT well-underway and two IND studies planned in the U.S. and now China, we're relentlessly pursing clinical development of an innovative CD19/BCMA dual-targeting approach, which seeks to offer differentiated efficacy over other investigational therapies that only target CD19. Combined with GC012F's consistently favorable safety profile, based on the data from 60 patients treated in IIT studies across three oncology indications, we have reason to believe that our candidate may offer promising advantages for people living with rSLE."

Several patient case studies in academia have shown CD19 CAR-T cell therapy to be feasible, tolerable and highly effective in a number of autoimmune diseases, including SLE. By targeting both CD19 and BCMA, it is believed that GC012F could enable deeper and wider depletion of disease-causing B-cells and plasma cells, potentially offering a more effective and longer-lasting treatment option for rSLE patients, especially those in severe and complicated disease condition.

GC012F is an autologous CAR-T therapeutic candidate dual-targeting B cell maturation antigen (BCMA) and CD19 and utilizes Gracell's proprietary FasTCAR next-day manufacturing platform. In addition to the upcoming rSLE IND studies, GC012F is being evaluated in a Phase 1b/2 IND study for the treatment of relapsed/refractory multiple myeloma (RRMM) in the U.S., and in four IIT studies for the treatment of rSLE, RRMM, newly-diagnosed multiple myeloma (NDMM) and B-NHL. In updated clinical results from the NDMM IIT, which were presented at the 65th American Society of Hematology Annual Meeting & Exposition in December 2023, GC012F demonstrated an overall response rate (ORR) of 100% and minimal residual disease negative stringent complete response (MRD- sCR) rate of 95.5%.

About GC012F

GC012F is Gracell's FasTCAR-enabled BCMA/CD19 dual-targeting autologous CAR-T cell therapy, which aims to transform cancer and autoimmune disease treatment by driving fast, deep and durable responses with an improved safety profile. GC012F is currently being evaluated in clinical studies in multiple hematological cancers as well as autoimmune diseases and has demonstrated a consistently strong efficacy and safety profile. Gracell has initiated a Phase 1b/2 trial evaluating GC012F for the treatment of relapsed or refractory multiple myeloma in the United States and a Phase 1/2 clinical trial in China is to be commenced imminently. An IIT has also been launched to evaluate GC012F for the treatment of refractory systemic lupus erythematosus (rSLE) and Investigational New Drug applications to study GC012F in rSLE have been cleared by the U.S. FDA and China NMPA.

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 therapy for cancer and autoimmune diseases, and improve outcomes for patients by enhancing effect, 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 than traditional CAR-T cells, making them more proliferative and effective at killing cancer cells. In 2022 and 2023, FasTCAR was named the winner of the Biotech Innovation category of the 2022 Fierce Life Sciences Innovation Awards and the Overall Immunology Solution of 2023 by BioTech Breakthrough 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 therapies for the treatment of cancers and autoimmune diseases. Leveraging its innovative FasTCAR and TruUCAR technology platforms and SMART CART™ 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 and autoimmune diseases. The lead candidate BCMA/CD19 dual-targeting FasTCAR-T GC012F is currently being evaluated in clinical studies for the treatment of multiple myeloma, B-NHL and SLE. For more information on Gracell, please visit www.gracellbio.com. Follow @GracellBio on LinkedIn.

Cautionary Note 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. The words "anticipate," "look forward to," "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 U.S. Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof. Gracell specifically disclaims any obligation to update any forward-looking statement, whether due to 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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