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 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 ☐

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 16, 2023

Exhibit 99.1

Gracell Biotechnologies Initiates Investigational Study Evaluating GC012F for Treatment of Refractory Systemic Lupus Erythematosus (SLE)

Gracell announces start of investigator-initiated trial to expand clinical evaluation of FasTCAR-T GC012F into autoimmune disease

GC012F pioneers the use of CD19/BCMA dual-targeting CAR-T in SLE, aiming for deeper and wider depletion of autoantibodies producing B-cells and plasma cells

SAN DIEGO, Calif., and SUZHOU and SHANGHAI, China, May 15, 2023 -- 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 and autoimmune diseases, today announced the initiation of an investigator-initiated trial (IIT) in China of GC012F, the Company's autologous FasTCAR therapeutic candidate dual-targeting B cell maturation antigen (BCMA) and CD19, for the treatment of refractory SLE.

“Our lead candidate GC012F leverages several next-generation CAR-T technologies including CD19/BCMA dual-targeting and the FasTCAR next-day manufacturing. This cell therapy candidate has demonstrated strong efficacy and consistently favorable safety in the treatment of several hematological malignancies, and we look forward to extending this potentially curative treatment option to patients with autoimmune diseases, such as SLE,” said William Cao, founder, Chairman and Chief Executive Officer of Gracell. “Patients with refractory SLE have limited options to treat their wide-ranging and often debilitating symptoms. This study of GC012F in SLE marks an important next step in GC012F’s development as we look to confirm its potential in autoimmune diseases and prepare the IND submission in both U.S. and China.”

SLE is a chronic autoimmune disease, in which the autoantibodies produced by the immune system attack the patient’s own tissues, causing multi-organ damage. SLE affects over three million people worldwide,[1] with disproportionate burden of disease seen among young women.[2] While immunosuppressants are used as the current standard of care, SLE remains a chronic condition that is difficult to manage, significantly impacts quality of life, and has no cure. Furthermore, refractory/severe SLE could lead to permanent organ damage, resulting in serious morbidity and even death. As such, there is urgent, high unmet medical need for more effective – and even curative – therapies, particularly to help manage refractory SLE.

GC012F has been studied in more than 50 patients across three hematological malignancy indications. In two studies on relapsed/refractory multiple myeloma (RRMM) and newly-diagnosed multiple myeloma (NDMM), GC012F has demonstrated fast, deep and durable responses and achieved 93.1% and 100% overall response rate (ORR), respectively. SLE is a new therapeutic area of interest for Gracell, as CD19 CAR-T has been reported in recent clinical research to be potentially “feasible, tolerable, and highly effective in this indication”.[3]

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[1] Tian, J., Zhang, D., Yao, X., Huang, Y., & Lu, Q. (2023). Global epidemiology of systemic lupus erythematosus: a comprehensive systematic analysis and modelling study. Annals of the Rheumatic Diseases, 82(3), 351-356

[2] Dall’Era M. Systemic lupus erythematosus. In: Imboden JB, Hellman DB, Stone JH. (Eds). Current Rheumatology Diagnosis and Treatment. 3rd ed. New York, NY:McGraw-Hill; 2013.

[3] Mackensen A, Müller F, Mougiakakos D, *et al.* Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus. *Nat Med* 28, 2124–2132 (2022). https://doi.org/10.1038/s41591-022-02017-5

Gracell's GC012F represents a novel approach entering human study for refractory SLE and pioneers the use of CD19/BCMA dual-targeting CAR-T in autoimmune disease. By targeting both CD19 and BCMA, GC012F could potentially enable deeper and wider depletion of autoantibodies producing B-cells and plasma cells, hence enhancing therapeutic outcomes in comparison to CD19-only approaches.

GC012F has a proven safety record in patients with RRMM, NDMM and B-NHL. No neurotoxicity or immune effector cell-associated neurotoxicity syndrome (ICANs) has been observed in any patients treated across three studies. 75% of patients in the NDMM study has not experienced cytokine release syndrome (CRS) of any grade, and in the RRMM study, patients experienced mostly low-grade CRS.

The FasTCAR next-day manufacturing platform technology could bring additional benefits to SLE patients as it shortens patient wait time, enhances CAR-T cell fitness, and reduces costs.

For more information on the study, please visit ClinicalTrials.gov using the identifier: NCT05846347.

About GC012F

GC012F is Gracell's FasTCAR-enabled BCMA/CD19 dual-targeting autologous CAR-T cell therapy, which aims to transform cancer and immunology treatment by driving fast, deep and durable responses with improved safety profile. GC102F is currently being evaluated in 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. Gracell has also initiated an investigator-initiated trial evaluating GC012F for the treatment of SLE.

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 and autoimmune 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 Refractory SLE

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage throughout the body, potentially impacting the joints, skin, brain, lungs, kidneys and blood vessels. SLE affects over 3 million people worldwide,[4] with disproportionate burden of disease seen among young women.[5] Immunosuppressants are the current standard of care, but early study data suggests that CAR-T cell therapy may be a potential treatment option.

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^{TM} 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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[4] Tian, J., Zhang, D., Yao, X., Huang, Y., & Lu, Q. (2023). Global epidemiology of systemic lupus erythematosus: a comprehensive systematic analysis and modelling study. Annals of the Rheumatic Diseases, 82(3), 351-356

[5] Dall'Era M. Systemic lupus erythematosus. In: Imboden JB, Hellman DB, Stone JH. (Eds). Current Rheumatology Diagnosis and Treatment. 3rd ed. New York, NY:McGraw-Hill; 2013.