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 April 2021

Commission file number: 001-39838

Gracell Biotechnologies Inc.

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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

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

Date: April 12, 2021

PRESS RELEASE

Gracell Biotechnologies Reports Long-term Follow-up Data on TruUCAR-enabled GC027 in Relapsed/Refractory T-ALL at the AACR 2021 Annual Meeting

SUZHOU and SHANGHAI, China, April 10, 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, today presented updated long-term follow-up data on their TruUCAR-enabled allogeneic product candidate GC027 for the treatment of adult patients with relapsed/refractory T-cell acute lymphoblastic leukemia (r/r T-ALL) in an e-poster presentation at the 2021 American Association for Cancer Research (AACR) Annual Meeting on April 10.

TruUCAR-enabled GC027 is a first-in-human, off-the-shelf allogeneic CAR-T stand-alone therapy targeting CD7. An ongoing, multi-center investigator-initiated Phase 1 trial in China is evaluating the safety and efficacy of GC027 for the treatment of adults with r/r T-ALL. We first reported results as oral presentation at the AACR 2020 Annual Meeting.

The updated data with a February 4, 2021 data cut-off represents long-term follow-up as well as additional patients treated. Patients had received a median of six prior lines of therapy and received a single infusion of TruUCAR GC027 in one of three dose levels: $0.6x10^7$cells/kg, $1.0x10^7$cells/kg or $1.5x10^7$cells/kg. Six patients (100%) treated achieved a complete remission with or without complete blood count recovery (CR/CRi) and five of the six patients (83%) achieved minimum residual disease negative complete remission (MRD- CR). At 6 months post treatment, three out of five patients (60%) had maintained MRD- CR. After 18.5 months of follow up for the initial patients treated, one patient continued to be MRD- CR at 16.8 months. One patient maintained MRD- CR until 9 months and one patient with primary refractory disease (no response to VDP) maintained his MRD- CR status until month 7. One additional patient treated presented initially with a high tumor burden and extensive extramedullary (EM) disease. After treatment with GC027 and as confirmed by PET CT scan, all EM lesions resolved. The patient achieved MRD- CR at day 28.

All six patients tolerated a single infusion of TruUCAR GC027. No neurotoxicity events (ICANS) or acute graft-versus-host disease (aGvHD) were observed. Cytokine release syndrome (CRS) occurred in all patients and was managed with standard of care including Tocilizumab. Overall safety findings were consistent with previous observations.

"These data show promising long-term follow-up results in r/r T-ALL patients who have very limited treatment options available," commented Dr. Martina Sersch, M.D., Chief Medical Officer of Gracell. "With these findings, GC027 may have the potential to be developed as a single- infusion stand-alone allogeneic CAR-T therapy. We are looking forward to expediting the clinical development of our TruUCAR-enabled GC027 globally, as well as expanding into additional indications beyond T-ALL."

Presentation link: https://cattendee.abstractsonline.com/meeting/9325/Presentation/4633

Abstract link: https://www.abstractsonline.com/pp8/#!/9325/presentation/4633

About GC027

TruUCAR-enabled GC027 is a first-in-human, off-the-shelf allogeneic CAR-T therapy targeting CD7, currently being developed for the treatment of T-ALL in adults. GC027 is manufactured from T cells of human leukocyte antigen (HLA) unmatched healthy donors. Developed on our proprietary TruUCAR platform, GC027 utilizes dual-function CAR to specifically target a patient's own T cells and natural killer (NK) cells that would otherwise be directed against the foreign, or allogeneic, CAR-T cells resulting in rejection by the patients. This novel design allows this allogeneic cell therapy to survive a patient's immune system without the need for combination treatment with additional potent immunosuppressant and represents a differentiated monotherapy approach.

About T-ALL

T cell malignancies are a group of cancers involving T lymphocytes, including acute T cell lymphoblastic leukemia or T-ALL. Standard of care treatment for T-ALL includes chemotherapy, radiation therapy and stem cell transplantation. Standard chemotherapy regimens only result in 30%—40% response rate with 6 months median Overall Survival among responders. Patients with T cell malignancies usually have high relapse and mortality rates. Relapsed patients have dismal prognosis with very limited treatment options and <10% of patients surviving beyond 5 years. Due to shared common surface antigens and potential contamination by malignant cells, development of CAR-T cell therapies for T-ALL is lagged behind. In addition, no new therapies have been approved for the treatment of T-ALL since the approval of Nelarabine (marketed by GlaxoSmithKline) by the FDA in 2005. Globally, approximately 64,000 patients are diagnosed with ALL every year with over approximately 6,000 expected to be diagnosed in the United States in 2020. T-ALL accounts for approximately 25% of ALL diagnoses in adults. [1]

About TruUCAR

TruUCAR is Gracell's proprietary technology platform and is designed to generate high-quality allogeneic CAR-T cell therapies that can be administered "off-the-shelf" at lower cost and with greater convenience. With differentiated design enabled by gene editing, TruUCAR is designed to control host vs graft rejection (HvG) as well as graft vs host disease (GvHD) without the need of being co-administered with immunosuppressive drugs.

The lead program of TruUCAR platform, GC027, is manufactured using T cells from non-HLA matched healthy donors. The TruUCAR platform utilizes novel designs of a dual-function CAR or dual-CAR to reduce HvG, eliminating the need of combination therapy with additional potent immunosuppressant to induce deeper immune suppression and enabling stand-alone allogeneic CAR-T cell therapy.

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

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1 D.I. Marks, C. Rowntree, Management of adults with T-cell lymphoblastic leukemia, Blood 2017

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: the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all, and other factors discussed in the “Risk Factors” section of the final prospectus filed 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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