PRESS RELEASE

Gracell Biotechnologies Doses First Patient in Phase 1b/2 Clinical Trial in U.S. Evaluating GC012F for Treatment of Relapsed/Refractory Multiple Myeloma

SAN DIEGO and SUZHOU, China and SHANGHAI, China, Sept. 26, 2023 (GLOBE NEWSWIRE) -- 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 first patient has been dosed in a Phase 1b/2 clinical trial evaluating its lead candidate, GC012F, in patients with relapsed or refractory multiple myeloma (RRMM) in the United States. GC012F is the Company's autologous therapeutic candidate dual-targeting B cell maturation antigen (BCMA) and CD19, developed on the proprietary FasTCAR next-day manufacturing platform.

The Phase 1b portion of the open-label multi-center trial has been initiated and will be conducted at several top medical centers in the United States. The study expects to enroll approximately 12 patients at two dose levels and is designed to evaluate the safety and tolerability of GC012F in RRMM patients, determine the recommended dose of GC012F for Phase 2 and characterize the pharmacokinetics of GC012F in RRMM patients. The Phase 2 portion is intended to evaluate the efficacy of GC012F in RRMM patients and further characterize the safety of GC012F. For more information about the Phase 1b/2 trial, please visit www.clinicaltrials.gov (identifier NCT05850234).

“Gracell has amassed a body of compelling evidence supporting the dual-targeting approach of GC012F for treatment of RRMM. Based on its fast, deep and durable responses as well as the differentiated safety profile observed in prior clinical studies, we firmly believe that GC012F has the potential to emerge as a leading treatment option and benefit patients across disease stages,” said Dr. William Cao, founder, Chairman and Chief Executive Officer of Gracell. “Dosing the first patient in the Phase 1b portion of the U.S. trial is another important step toward validating this treatment for RRMM patients. We are grateful to everyone involved in this clinical study, including the investigators, clinical and manufacturing teams and many others who collaborated seamlessly to expedite the prompt treatment of the first patient. Most of all, I’d like to thank the patients, and their loved ones, for participating in this trial.”

GC012F has been studied in more than 50 patients across three hematological malignancy indications, RRMM, newly diagnosed multiple myeloma (NDMM) and B-cell non-Hodgkin's lymphoma in investigator-initiated trials (IIT), demonstrating fast, deep and durable responses. It is also being evaluated for treatment of refractory systemic lupus erythematosus (rSLE) in an IIT. Latest clinical data from GC012F in the treatment of RRMM has been presented at the American Society for Clinical Oncology (ASCO) and the European Hematology Association (EHA) annual meetings. As of the data cutoff date of April 12, 2023, among 29 predominantly high-risk RRMM patients, GC012F achieved a 93.1% overall response rate (ORR), a stringent complete response rate of 82.8%, with a median progression free survival of 38 months (95% CI: 11.8-NR). The safety profile was consistently favorable, with no neurotoxicity of any grade, and no second primary malignancy reported with this longer-term follow-up.

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 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 RRMM in the United States and a Phase 1/2 clinical trial in China is to be commenced imminently. Gracell has also launched an IIT evaluating GC012F for the treatment of rSLE.

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 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 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 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 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 systemic lupus erythematosus (SLE). 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. 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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