PRESS RELEASE

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

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

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

SAN DIEGO and SUZHOU, China and SHANGHAI, China, Nov. 27, 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 U.S. Food and Drug Administration (FDA) has cleared Gracell's Investigational New Drug (IND) application, allowing the Company to initiate a Phase 1/2 clinical trial of FasTCAR-T GC012F in the United States for the treatment of refractory systemic lupus erythematosus (rSLE).

"We are excited to expand the clinical development of our lead FasTCAR asset, GC012F, for treatment of rSLE in the United States," said Dr. William Cao, founder, Chairman and Chief Executive Officer of Gracell. "This progress marks the second U.S. IND clearance for GC012F, a notable milestone. As a next-generation CAR-T therapy, GC012F combines the innovative CD19/BCMA dual-targeting approach and our breakthrough FasTCAR next-day manufacturing technology, both of which could potentially provide meaningful benefits to SLE patients. Additionally, what sets GC012F apart is its consistently favorable safety profile demonstrated by the absence of neurotoxicity in 60 patients treated across three IIT studies. We look forward to developing GC012F as a transformative therapy for SLE patients, who are in urgent need of highly effective and safe treatment options."

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 study, GC012F is being evaluated in the 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. Updated clinical results from the NDMM IIT, which will be presented at the 65th American Society of Hematology Annual Meeting & Exposition in December 2023, demonstrates an overall response rate (ORR) of 100% and minimal residual disease negative stringent complete response (MRD- sCR) rate of 95.5%.

The Phase 1 portion of the Phase 1/2 clinical trial evaluating GC012F in rSLE will be initiated in 2024 and is designed to assess the safety and tolerability of GC012F, determine the recommended dose for Phase 2 study and characterize the pharmacokinetics of GC012F in this patient population.

Systemic lupus erythematosus (SLE) is a B-cell-mediated autoimmune disease, in which autoantibodies produced by the immune system attack the patient's own tissues, causing multi-organ damage. 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. There is an urgent, high unmet medical need for more effective – and even curative – therapies, particularly to help manage 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 therapeutic approach for rSLE. Further, in preclinical studies, GC012F has shown a more effective elimination of antibody secreting cells compared to CD19 single-targeted CAR-T therapy.

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 RRMM 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 rSLE and the IND application to study GC012F in rSLE has been cleared by the U.S. FDA.

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 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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