PRESS RELEASE

Gracell Biotechnologies Announces FDA Clearance of IND Application for Phase 1 Clinical Trial of FasTCAR-T GC012F as Early-Line Treatment of Multiple Myeloma

Further expands clinical development of FasTCAR-T GC012F in multiple myeloma amid ongoing U.S. trial evaluating therapy for treatment of relapsed/refractory multiple myeloma

SAN DIEGO and SUZHOU, China and SHANGHAI, China, Jan. 29, 2024 (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 clinical trial of GC012F in the United States for the early-line treatment of multiple myeloma (ELMM).

"We are extremely pleased to receive our third U.S. IND clearance for our lead FasTCAR candidate GC012F, now expanding company-sponsored investigation into early-line multiple myeloma," said Dr. William Cao, founder, Chairman and Chief Executive Officer of Gracell. "This IND marks an exciting milestone as we extend efforts to address significant unmet needs earlier in multiple myeloma treatment through GC012F's unique dual-targeting approach and FasTCAR manufacturing, which have already shown great promise for deeper, durable responses. It also clears the path toward generating safety and efficacy data specifically in ELMM patients, providing us with the opportunity to better explore and define GC012F's potential role across this initial treatment setting where there is a deep need to drive improved, sustained outcomes."

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. This is the third U.S. IND clearance for GC012F. In addition to the ELMM study, GC012F is being evaluated in an ongoing Phase 1b/2 U.S. IND study for the treatment of relapsed/refractory multiple myeloma (RRMM) and in a Phase 1/2 clinical trial for the treatment of refractory systemic lupus erythematosus (rSLE) that will initiate in 2024. GC012F is also being evaluated in four investigator-initiated trials (IIT) for the treatment of rSLE, RRMM, newly-diagnosed multiple myeloma (NDMM) and B-cell non-Hodgkin lymphoma (B-NHL).

In updated clinical results from the NDMM IIT presented at the 65th American Society of Hematology Annual Meeting & Exposition in December 2023, GC012F demonstrated an overall response rate of 100% and minimum residual disease negative stringent complete response 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 seeking to drive 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 applications to study GC012F in rSLE have been cleared by the U.S. FDA and China's National Medical Products Administration, respectively. Additionally, a new IND application for GC012F in ELMM has also 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.

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