PRESS RELEASE

Gracell Biotechnologies Announces FDA Clearance of the IND Application for Phase 1b/2 Clinical Trial of FasTCAR-T GC012F for the Treatment of Relapsed/Refractory Multiple Myeloma

BCMA/CD19 dual-targeting FasTCAR-T GC012F has demonstrated deep responses and favorable safety profile in proof of concept clinical studies

Company plans to initiate Phase 1b/2 clinical trial in the U.S. in second quarter of 2023

SAN DIEGO Calif., and SUZHOU and SHANGHAI, China, Feb. 3, 2023 /PRNewswire/ -- 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, today announced that the U.S. Food and Drug Administration (FDA) has cleared Gracell's Investigational New Drug (IND) application and the Company can proceed to initiate a Phase 1b/2 clinical trial in the U.S. of GC012F, an autologous CAR-T therapeutic candidate, for the treatment of relapsed/refractory multiple myeloma (RRMM).

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 November 2021, the FDA granted GC012F Orphan Drug Designation for the treatment of multiple myeloma. GC012F is currently being studied in multiple investigator-initiated trials (IIT) evaluating its safety and efficacy in RRMM, newly-diagnosed multiple myeloma, and B-cell non-Hodgkin's lymphoma. At the European Hematology Association 2022 Hybrid Congress, Gracell presented longer-term follow-up clinical data of GC012F in RRMM that showed a 100% minimal residual disease (MRD) negativity rate in all patients treated.

Gracell plans to initiate a Phase 1b/2 clinical trial in the second quarter of 2023 in the U.S. to further evaluate GC012F in RRMM patients. The Phase 1b portion of the trial 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.

"Advancing our lead therapeutic candidate into a U.S. clinical trial is major milestone for Gracell, and further validates our GC012F program, proprietary FasTCAR next-day manufacturing platform and novel dual-targeting approach," said Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. "Having demonstrated deep responses and a favorable safety profile across indications, GC012F continues showing strong potential to become a transformative therapy. We look forward to initiating the Phase 1b/2 clinical trial and to bringing this promising therapeutic candidate one step closer to patients in need."

About GC012F

GC012F is a FasTCAR-enabled BCMA/CD19 dual-targeting CAR-T product candidate that is currently being evaluated in IIT studies in China for the treatment of multiple myeloma and B-cell non-Hodgkin's lymphoma. GC012F simultaneously targets CD19 and BCMA to drive fast, deep and durable responses, which can potentially improve efficacy and reduce relapse in multiple myeloma and B-NHL patients.

About FasTCAR

CAR-T cells manufactured on Gracell's proprietary FasTCAR platform appear younger, less exhausted and show enhanced proliferation, persistence, bone marrow migration and tumor cell clearance activities as demonstrated in preclinical studies. With next-day manufacturing, FasTCAR is able to significantly improve cell production efficiency which may result in meaningful cost savings, and,

together with fast release time, enables enhanced accessibility of cell therapies for cancer patients.

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 and SMART CART^{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 http://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," "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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