PRESS RELEASE

Gracell Biotechnologies Presents Clinical Data for FasTCAR-T GC012F for High Risk, Newly Diagnosed Multiple Myeloma Demonstrating 100% Overall Response Rate

BCMA/CD19 dual-targeting FasTCAR-T GC012F data from ongoing clinical trial presented at 64th American Society of Hematology Annual Meeting and Exposition

SAN DIEGO and SUZHOU and SHANGHAI, China, Dec. 10, 2022 /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 the clinical data from its ongoing Phase 1, investigator-initiated trial (IIT) in China evaluating FasTCAR-enabled GC012F as first-line therapy in transplant-eligible, high-risk, newly diagnosed multiple myeloma (NDMM) patients. Data has been presented in an oral session at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition, held Dec. 10-13 in New Orleans. Patients in the study achieved a 100% overall response rate (ORR) and 100% minimal residual disease (MRD) negativity in all dose levels.

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.

As of the Oct. 14, 2022 data cutoff date, 16 transplant-eligible NDMM patients had received GC012F infusion in the clinical trial. All patients had multiple high-risk features. After receiving a conditioning lymphodepletion regimen of cyclophosphamide and fludarabine, patients were treated with GC012F as a single infusion with one of three dose levels: 1x10^5 cells/kg, 2x10^5 cells/kg and 3x10^5 cells/kg.

As of Oct. 14, 2022, among the 16 evaluable patients with the median follow-up time of eight months (ranging from 1.3 to 15.4 months):

- ORR was 100%
- 87.5% (14/16) of patients achieved stringent complete response (sCR). Patients continue to be followed for deepening responses
- 100% of evaluable patients achieved MRD negativity in all dose levels
- 100% of evaluable patients achieved MRD negativity at months 1, 6 and 12
- 100% of patients experienced robust CAR-T cell expansion with long persistence in all dose levels

The clinical data also demonstrated an excellent safety profile:

- Only 25% (4/16) of patients experienced Grade 1-2 cytokine release syndrome (CRS); no patients experienced Grade 3-5 CRS
- No immune effector cell-associated neurotoxicity syndrome (ICANS) or other neurotoxicity of any grade had been observed

"This clinical data brings us great optimism. GC012F has demonstrated an impressive 100% ORR, 100% MRD negativity and 87.5% sCR, as well as an outstanding safety profile, among newly-diagnosed multiple myeloma patients, showing tremendous potential for substantial improvement over currently available therapies," said Dr. Wendy Li, Gracell's Chief Medical Officer. "We are pleased to share this data with the leading experts in hematology and oncology at ASH 2022. We believe that the data underscores GC012F's significant potential as a safe and effective therapy for NDMM patients. In addition, GC012F is developed using our proprietary FasTCAR next-day manufacturing platform, which could greatly expedite the delivery of this much-needed therapy to patients."

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™ 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 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.

Media contacts
Marvin Tang
marvin.tang@gracellbio.com
Kyle Evans
kyle.evans@westwicke.com

Investor contacts
Gracie Tong
gracie.tong@gracellbio.com
Stephanie Carrington
stephanie.carrington@westwicke.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/gracell-biotechnologies-presents-clinical-data-for-fastcar-t-gc012f-for-high-risk-newly-diagnosed-multiple-myeloma-demonstrating-100-overall-response-rate-301698921.html

SOURCE Gracell Biotechnologies Inc.