PRESS RELEASE

Gracell Biotechnologies Presents Longer-Term Results for FasTCAR-T GC012F in B-Cell Non-Hodgkin's Lymphoma at EHA2023, Highlighting 100% Overall Response Rate

Data on CD19/BCMA dual-targeting FasTCAR-T GC012F showed 100% overall response rate (ORR) and 66.7% 6-month complete response (CR) rate among treated patients, all with diffuse large B-cell lymphoma (DLBCL) subtype

Data on GC012F for treatment of relapsed/refractory multiple myeloma (*RRMM) and donor-derived CAR-T GC007g for treatment of* relapsed/refractory B-cell acute lymphoblastic leukemia (r/r *B-ALL) have been presented as posters on June 9 at EHA2023*

SAN DIEGO, Calif., and SUZHOU and SHANGHAI, China, June 10, 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 presented longer-term follow-up data from a first-in-human study evaluating GC012F, a CD19 and B-cell maturation antigen (BCMA) dual-targeted autologous CAR-T therapeutic candidate, in patients with relapsed/refractory B-cell non-Hodgkin's Lymphoma (r/r B-NHL) as an oral presentation (abstract #S234) at the European Hematology Association (EHA2023) Congress.

While CD19-directed CAR-T cell therapy has been demonstrated to be a valuable treatment option for r/r B-NHL, other studies have identified that 39% to 97% of clinical B-NHL samples express BCMA as well.[1,2,3] To further improve safety and efficacy of NHL treatment, Gracell is exploring the clinical potential of GC012F, a CD19 and BCMA dual-targeting CAR-T cell therapy, for treatment of r/r B-NHL. GC012F is manufactured through a novel next-day FasTCAR process and demonstrated a younger phenotype of CAR-T cells and highly effective tumor killing activity in preclinical animal models.

In the single-arm, open label investigator-initiated trial (IIT), nine r/r B-NHL patients were enrolled and treated with GC012F, and completed at least three months of follow-up. Doses range between $3.7x10^4$ to $3x10^5$ CAR-T cells/kg. All nine patients are classified as relapsed/refractory DLBCL. All patients' lymphoma samples expressed CD19, and samples from seven out of eight tested patients expressed BCMA.

As of the April 12, 2023 data cutoff date, with a median follow-up of 293 days (range: 131-546 days), patients treated with GC012F achieved a high response rate and outstanding durability of response:

- 100% (9/9) overall response rate (ORR) at 3 months among nine patients with r/r DLBCL;
- 77.8% (7/9) complete response (CR) rate at 3 months;
- 66.7% (6/9) CR rate at 6 months;
- GC012F CAR-T cells were detectable in tumor biopsies from all tested patients, indicating the infiltration of CAR-T cells into the tumor lesions.

GC012F also continued to show a favorable safety profile:

- Cytokine release syndrome (CRS) was mostly Grade 1 (56%; 5/9). Grade 3 CRS was observed in one patient (duration of 2 days) with quick recovery after standard of care treatment. No Grade 4/5 CRS events occurred;
- No neurotoxicity or immune effector cell-associated toxicity (ICANS) of any grade were observed.

"One year after we reported initial data from the IIT evaluating FasTCAR-T GC012F in B-NHL at EHA2022, we are proud to be back at EHA presenting longer-term results from more patients as an oral presentation," said Dr. Wendy Li, Chief Medical Officer of Gracell. "Durable responses, enhanced safety, and timely access to cell therapy remain significant unmet needs for NHL patients. With a 100% ORR at 3 months and CR rates of 78% at 3 months and 67% at 6 months, particularly among DLBCL patients, the updated data further support the clinical potential and wide applicability of GC012F, and the benefits of a CD19/BCMA dual-targeting approach combined with FasTCAR next-day manufacturing."

Gracell is also evaluating GC012F in RRMM, newly-diagnosed multiple myeloma (NDMM), and systemic lupus erythematosus (SLE).

On June 9, Gracell also presented the following during poster sessions:

- First results from a Phase 1 study of the donor-derived allogeneic CAR-T GC007g (abstract #P369), showing 100% ORR and a favorable safety profile for treatment of r/r B-ALL;

- Updated results from the IIT evaluating GC012F for the treatment of RRMM (abstract #P869), which were also presented as an oral presentation at the 2023 ASCO Annual Meeting. The data demonstrated 100% minimal residual disease (MRD) negativity and 82.8% MRD negative stringent complete response (sCR) in a predominantly high-risk RRMM population.

Additional information about the presentations and the EHA2023 Hybrid Congress is available on the EHA website.

[1] Blood Cancer Journal (2020); 10:73.
[2] Blood (2017); 130:2755.
[3] Hum Gene Ther (2018); 29(5): 585.

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. GC102F is currently being evaluated in investigator-initiated trials in multiple hematological cancers as well as autoimmune disease, and has demonstrated a consistently strong efficacy and safety profile. In February 2023, Gracell announced regulatory clearance of Investigational New Drug applications in the United States and China to commence clinical trials evaluating GC012F for the treatment of relapsed/refractory multiple myeloma. Gracell has also initiated an investigator-initiated trial evaluating GC012F for the treatment of SLE.

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 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. Leveraging its pioneering 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 disease. 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. These statements include, but are not limited to, statements relating to the expected trading commencement and closing date of the offering. 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 Jessica Laub jessica.laub@westwicke.com Investor contacts Gracie Tong gracie.tong@gracellbio.com Stephanie Carrington stephanie.carrington@westwicke.com