



Gracell Biotechnologies Announces Multiple Advancements of TruUCAR Allogeneic CAR-T Platform

Abstract providing early first-in-human data on GC502 accepted for presentation at American Association for Cancer Research (AACR) Annual Meeting 2022

SUZHOU, China, and PALO ALTO, Calif., Feb. 22, 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 multiple advancements of its TruUCAR platform, the Company's proprietary technology platform designed to generate high-quality allogeneic CAR-T cell therapies that can be administered "off-the-shelf" as stand-alone therapy at lower cost and with greater convenience.



An abstract providing early results of a first-in-human clinical study on GC502 in r/r B-ALL patients has been accepted for poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2022 in New Orleans, Louisiana. GC502 is an allogeneic CD19/CD7 dual-directed chimeric antigen receptor (CAR) T cell therapy currently under development for multiple indications including B-ALL. GC502 is currently being studied in a Phase 1 investigator-initiated trial (IIT) in China for patients with B-cell malignancies. This product candidate leverages the novel dual-CAR design of Gracell's proprietary TruUCAR platform, which allows the CD19 CAR to target malignant cells, while the CD7 CAR is designed to suppress host versus graft rejection response, enabling GC502 to be a stand-alone therapy without the need of additional therapies to suppress host versus graft rejection after successful lymphodepletion. The complete title of the abstract will be posted to the AACR Online Itinerary Planner at 4:30PM ET on Tuesday, March 8, 2022 and the text of abstract will be posted on Friday, April 8, 2022.

Another lead product candidate of the TruUCAR platform is GC027, an allogeneic CAR-T therapy targeting CD7 for the treatment of adults with T-cell lymphoblastic leukemia (T-ALL). Gracell is currently investigating GC027 in a Phase 1 IIT study in China evaluating the safety and efficacy. Early data had been reported at previous conferences and manuscripts. Both GC502 and GC027 are poised to strengthen the allogeneic platform approach of TruUCAR.

"We are excited to present our preliminary data for GC502, our second TruUCAR-T product candidate, in patients with r/r B-ALL at the AACR annual meeting," said Dr. Martina Sersch, Chief Medical Officer of Gracell. "With our TruUCAR platform, Gracell aims to address multiple challenges associated with autologous CAR-T products including availability, speed to therapy and cost. We believe the strides we are making with GC502 and GC027 are important steps forward in developing allogeneic CAR-T products further and look forward to updating the oncology community on our progress at the AACR Annual Meeting 2022. In addition, enrollment on the IIT for GC027 in patients with T-ALL will be concluded to summarize the clinical findings."

"GC502 is the second product in development based on our innovative TruUCAR platform. We are very pleased to see the preliminary clinical evidence that applicability of TruUCAR platform to additional disease indications could potentially be manifold by switching the second CAR against the tumor antigens selected. We look forward to continued development of additional off-the-shelf CAR-T therapies based on this platform," said Dr. William (Wei) Cao, Founder and Chief Executive Officer of Gracell.

About GC502

GC502 is a TruUCAR-enabled CD19/CD7 dual-directed, off-the-shelf allogeneic CAR-T product candidate that is being studied for the treatment of B-cell malignancies. GC502 is manufactured using T cells from non-human leukocyte antigen (HLA) matched healthy donors. An enhancer molecule is embedded in the basic construct of TruUCAR to enhance proliferation of TruUCAR T cells. Optimized for CD19/CD7 dual-CAR functionality and *in vivo* durability, GC502 has demonstrated robust anti-tumor efficacy with promising potential

to suppress host versus graft (HvG) rejection in preclinical models.

About B-ALL

Acute lymphoblastic leukemia (ALL) is a type of blood cancer characterized by proliferation of immature lymphocytes in the bone marrow, which can involve either T lymphocytes (T-ALL), or B lymphocytes (B-ALL). Globally, approximately 64,000 patients are diagnosed with ALL every year with approximately 6,000 diagnosed in the United States, and approximately 7,400 diagnosed in China in 2020^[1]. B-ALL accounts for 85%-88% of ALL diagnoses.

About GC027

TruUCAR-enabled GC027 is a first-in-human, off-the-shelf allogeneic CAR-T therapy targeting CD7, currently being developed for the treatment of T-ALL in adults. GC027 is manufactured from T cells of non-HLA matched healthy donors. Developed on our proprietary TruUCAR platform, GC027 utilizes dual-function CAR to specifically target a patient's own T cells and natural killer (NK) cells that would otherwise be directed against the foreign, or allogeneic, CAR-T cells resulting in rejection by the patients. This novel design allows this allogeneic cell therapy to survive a patient's immune system without the need for combination treatment with additional potent immunosuppressant and represents a differentiated monotherapy approach. Additional information about the study is available at www.clinicaltrials.gov using identifier: NCT04264078.

About T-ALL

T-cell malignancies are a group of cancers involving T lymphocytes, including acute T-cell lymphoblastic leukemia or T-ALL. Standard of care treatment for T-ALL includes chemotherapy, radiation therapy and stem cell transplantation. Standard chemotherapy regimens only result in 30%- 40% response rate with 6 months median overall survival among responders. Patients with T-cell malignancies usually have high relapse and mortality rates. Relapsed patients have dismal prognosis with very limited treatment options and <10% of patients surviving beyond 5 years. Due to shared common surface antigens and potential contamination by malignant cells, development of CAR-T cell therapies for T-ALL is lagged behind. In addition, no new therapies have been approved for the treatment of T-ALL since the approval of Nelarabine (marketed by GlaxoSmithKline) by the FDA in 2005. Globally, approximately 64,000 patients are diagnosed with ALL every year with over approximately 6,000 expected to be diagnosed in the United States in 2020. T-ALL accounts for approximately 25% of ALL diagnoses in adults^[2].

About TruUCAR

TruUCAR is Gracell's proprietary technology platform and is designed to generate high-quality allogeneic CAR-T cell therapies that can be administered "off-the-shelf" at lower cost and with greater convenience. With differentiated design enabled by gene editing, TruUCAR is designed to control host versus graft rejection (HvG) as well as graft versus host disease (GvHD) without the need for being co-administered with immunosuppressive drugs. The novel dual-CAR design allows tumor antigen-CAR moiety to target malignant cells, while the CD7 CAR moiety is designed to suppress HvG response, enabling TruUCAR T cell to be a stand-alone therapy.

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, TruUCAR and SMART CAR™ technology platforms, 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 production 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](https://www.linkedin.com/company/gracell-bio).

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.

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[1] Data source: Clarivate | DRG: Acute Lymphoblastic Leukemia - Epidemiology

[2] D.I. Marks, C. Rowntree, Management of adults with T-cell lymphoblastic leukemia, Blood 2017

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