# PRESS RELEASE

## Gracell Biotechnologies to Present Clinical Data on BCMA/CD19 Dual-targeting CAR-T GC012F in RRMM and B-NHL and CD19/CD7 Dual-directed Allogeneic CAR-T GC502 in B-ALL at EHA2022 Congress

SAN DIEGO, Calif., SUZHOU and SHANGHAI, China , May 12, 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 details of three abstracts that it will present at the European Hematology Association 2022 Hybrid Congress (EHA2022 Congress), being held from June 9 – June 12 in Vienna, Austria. The abstracts highlight the clinical data from ongoing investigator-initiated trials (IITs) of BCMA/CD19 dual-targeting FasTCAR candidate GC012F in two indications of B-cell non-hodgkin's lymphoma (B-NHL) and relapsed/refractory multiple myeloma (RRMM), and allogeneic TruUCAR candidate GC502 in B-cell acute lymphoblastic leukemia (B-ALL).

"We are very excited to share our data for both our FasTCAR candidate GC012F in two indications of RRMM and B-NHL, and allogeneic TruUCAR candidate GC502 in B-ALL at the EHA2022 Congress," said Dr. Martina Sersch, Chief Medical Officer of Gracell. "The new data, including the expanded indication of GC012F into B-NHL, demonstrates the potential of our platforms and provides further validation. The clinical data of BCMA/CD19 dual-targeting GC012F in the treatment of B-NHL shows promising early results, along with benefits of the next-day manufacturing enabled by the FasTCAR platform. The CD19/CD7 dual-directed CAR-T therapy GC502 is our second allogeneic candidate on our TruUCAR platform, demonstrating the potential wide applicability of the TruUCAR design."

**BCMA/CD19 Dual-Targeting FasTCAR-T GC012F for the Treatment of B-NHL**

GC012F is an autologous CAR-T therapeutic candidate dual-targeting B cell maturation antigen (BCMA) and CD19. It is developed using Gracell's proprietary FasTCAR platform which enables next-day manufacturing, and is currently being evaluated in IITs in China including in RRMM and B-NHL. GC012F is the first BCMA/CD19 dual-targeting CAR-T in human trials for B-NHL.

Gracell will present the early results of the first-in-human phase 1 IIT in China evaluating the safety and tolerability of GC012F in B-NHL patients. Three patients who had received a median of two prior lines of therapy were enrolled, all of which presented with bulky disease. As of the February 22, 2022 data cutoff date, the enrolled patients had received one single infusion of GC012F at three different doses of $3.7x10^4$ cells/kg and $2\text{-}3x10^5$ cells/kg.

All three patients had achieved a complete response (CR) confirmed by PET- CT at day 28 after GC012F infusion. At 3-month follow-up, both of the two assessable patients had ongoing response. No dose-limiting toxicities were observed and no immune effector cell-associated neurotoxicity syndrome (ICANS) were observed. CRS presented as Grade 1 in two patients and Grade 3 in one patient (duration of two days) with no Grade 4 or 5 events.

Details of the presentation are as follows:

- **Abstract title:** First-in-human study of CD19/BCMA dual-targeting FasTCAR-T GC012F for patients with relapsed/refractory B-cell non-Hodgkin's lymphoma
- **Session title:** Poster session
- **Presentation time:** Friday, June 10 from 4:30 – 5:45 PM CEST

**BCMA/CD19 Dual-Targeting FasTCAR-T GC012F for the Treatment of RRMM**

Gracell will also present as an oral abstract presentation the updated results from the first-in-human IIT evaluating GC012F for the

treatment of RRMM patients. This data is currently under embargo and will be published on the EHA2022 Hybrid Congress website on Thursday, May 26 concurrently with ASCO.

Details of the presentation are as follows:

- **Abstract title:** Updated results of a multicenter first-in-human study of BCMA/CD19 dual-targeting FasTCAR-T GC012F for patients with relapsed/refractory multiple myeloma (RRMM)
- **Session title:** Relapsed/refractory myeloma: BCMA-directed therapies
- **Presentation time:** Sunday, June 12 from 11:30 AM – 12:45 PM CEST
- **Presentation location:** Hall A2-A3

**CD19/CD7 Dual-directed Allogeneic TruUCAR-T GC502 for the Treatment of B-ALL**

GC502 leverages the novel dual-directed CAR design of Gracell's proprietary TruUCAR platform, designed to generate high-quality allogeneic CAR-T cell therapies that can be administered "off-the-shelf" at lower cost and with faster patient's access. TruUCAR-enabled GC502 utilizes the dual-directed CAR design with one CAR targeting CD19 on malignant cells and a second CAR targeting CD7 to suppress host-versus-graft rejection. An enhancer molecule is embedded in the basic construct of TruUCAR to enhance proliferation of TruUCAR T cells.

Between September 2021 and January 2022, four r/r B-ALL patients were enrolled and treated in an open-label, non-randomized, prospective IIT in China in two different dose levels and with two different formulations. Patients were heavily pretreated, and all had previously received either autologous or donor derived CD19 or CD19/CD22 targeted CAR-T therapy. As of the January 28, 2022 data cutoff date, all four patients had received a single dose of GC502, including one patient at dose level 1 (DL1) $1.0x10^7$ cells/kg and three patients at dose level 2 (DL2) $1.5x10^7$ cells/kg. Patients received a Flu/Cy based lymphodepletion regimen prior to treatment with GC502.

Three of four patients achieved minimal residual disease negative complete response or complete response with incomplete count recovery (MRD- CR/CRi), and one patient achieved a partial response at month one and subsequently received allogeneic hematopoietic stem-cell transplantation (allo-HSCT) on day 39.

Cytokine release syndrome (CRS) presented as Grade 2 and Grade 3 with no Grade 4 or 5 events. No immune effector cell-associated neurotoxicity syndrome (ICANS) or acute graft-versus-host disease (aGvHD) were observed.

Details of the presentation are as follows:

- **Abstract title:** Early results of a safety and efficacy study of allogeneic TruUCAR$^{TM}$ GC502 in patients with relapsed/refractory B-cell acute lymphoblastic leukemia (R/R B-ALL)
- **Session title:** Poster session
- **Presentation time:** Friday, June 10 from 4:30 – 5:45 PM CEST

For more information about the EHA2022 Hybrid Congress, visit www.ehaweb.org.

**About GC012F**

GC012F is a FasTCAR-enabled 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 B-NHL**

Non-Hodgkin's lymphoma (NHL) is a group of blood cancers that developed from lymphocytes, most commonly derived from B cells (B-NHL). Globally, approximately 510,000 patients are diagnosed with NHL every year with about 80,470 patients expected to be diagnosed with NHL in the United States in 2022[1]. B-NHL accounts for approximately 85% of NHL diagnoses.

[1] Data source: American Cancer Society

**About GC502**

GC502 is a TruUCAR-enabled CD19/CD7 dual-directed, off-the-shelf allogeneic CAR-T product candidate that is being studied in an ongoing Phase 1 IIT in China 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 effects with 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 an estimated 6,660 new cases to be diagnosed in the United States in 2022[2]. B-ALL accounts for 75% of ALL diagnoses in adults.

[2] Data source: American Cancer Society

**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 turnaround time, enables enhanced accessibility of cell therapies for cancer patients.

**About TruUCAR**

TruUCAR is Gracell's proprietary technology platform and is designed to generate CAR-T cell therapies from high quality allogeneic T cells that can be administered "off-the-shelf" at lower cost and with improved accessibility of cell therapies for cancer patients. With differentiated design enabled by gene editing, TruUCAR is designed to control HvG as well as GvHD without the need for being co-administered with additional strong immunosuppressant after conventional lymphodepletion. The novel dual-CAR design allows tumor antigen-CAR moiety to target malignant cells, while the CD7 CAR moiety is designed to suppress rejection (HvG response) of allogeneic CAR-T cells by host T and NK cells (HvG).

**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. 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.

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