

Gracell Biotechnologies to Present Preclinical Results of TruUCAR-enabled CD19/CD7 Dual-Directed Allogeneic CAR-T Cell Therapy (GC502) for B-Cell Malignancies at the 63rd ASH Annual Meeting

SUZHOU and SHANGHAI, China, and PALO ALTO, California, Nov. 4, 2021 /PRNewswire/ -- Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell"), a global clinical-stage biopharmaceutical company dedicated to developing highly efficacious and affordable cell therapies for the treatment of cancer, today announced preclinical data for GC502, an allogeneic chimeric antigen receptor (CAR) T cell therapy for the treatment of B-cell malignancies, will be presented as a virtual poster at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition as part of the "Cellular Immunotherapies: Basic and Translational" session on December 11, 2021 from 5:30 p.m.-7:30 p.m.(EST).



GC502 is a CD19/CD7 dual-directed, stand-alone off-the-shelf allogeneic CAR-T therapy for the treatment of B-cell malignancies developed on Gracell's proprietary TruUCAR technology platform. The novel dual CAR design allows the CD19 CAR moiety to target malignant cells, while the CD7 CAR moiety is designed to suppress host versus graft (HvG) (rejection) response, enabling GC502 to be a stand-alone therapy. Preclinical results demonstrate robust anti-tumor efficacy and promising potential to suppress HvG disease without the need for additional immunosuppressive therapeutics.

TruUCAR is Gracell's proprietary technology platform designed to generate high-quality allogeneic CAR-T therapies using T cells from non-HLA matched healthy donors, manufactured in large quantities as "off-the-shelf" products at a lower cost.

"Encouraging preclinical data with GC502 validates the functionality of dual CAR developed on our TruUCAR platform and highlights the potential of our proprietary off-the-shelf, stand-alone allogeneic therapies for a broad range of patients." Said Dr. Xinxin Wang, Vice President, Research and Development at Gracell.

"GC502 displays strong anti-tumor potency and suppression of HvG response in the preclinical study. We look forward to further clinical development of GC502 and expanding our early-stage pipeline with more safe, effective and accessible cell therapies for tough to treat hematological malignancies." Commented Dr. Lianjun Shen, Senior Vice President, Head of Research and Development at Gracell.

Details on the poster presentation are shown below:

2021 63rd ASH Annual Meeting and Exposition

Abstract 148500: Preclinical Results of an Allogeneic, Universal CD19/CD7-Targeting CAR-T Cell Therapy (GC502) for B Cell Malianancies

Abstract Release Time: 9:00 a.m., November 4, 2021

Presentation Session: Cellular Immunotherapies: Basic and Translational **Poster Presentation Time**: 5:30 p.m., -7:30 p.m., December 11, 2021

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, including B-ALL and B-NHL. GC502 is manufactured using T cells from non-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 vs graft (HvG) rejection in preclinical models.

About B-ALL and B-NHL

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.

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 over 77,000 patients diagnosed in the United States, and approximately 68,000 diagnosed in China in 2020[2]. B-NHL accounts for approximately 85% of NHL diagnoses.

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 vs 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 host versus graft (HvG) response, enabling TruUCAR T cell to be a stand-alone therapy.

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

[2] Data source: Clarivate | DRG: Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia - Epidemiology

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, 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.

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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