



Gracell Biotechnologies to Present Data Highlighting Preclinical Efficacy of SMART CART™ Against Solid Tumors at Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting

Novel, proprietary technology designed to strengthen the functionality of CAR-T cells against solid tumors

SMART CAR-T cells demonstrated resistance to immunosuppressive tumor microenvironment (TME) and maintained long-term proliferation and cytotoxicity both in vitro and in vivo

Launching investigator-initiated trial (IIT) of SMART CART GC506 targeting Claudin 18.2 positive tumors

SAN DIEGO and SUZHOU, China and SHANGHAI, China, Oct. 31, 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, announced today preclinical data from the Company's SMART CART™* technology for solid tumors will be presented as a poster at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting, taking place November 1-5, 2023, in San Diego and online.

"Gracell has long been dedicated to unlocking the tremendous potential of CAR-T therapy against solid tumors in our pursuit of transformative cell therapies. We are thrilled to present the encouraging preclinical data from SMART CART, our next-generation solid tumor technology," said Dr. Lianjun Shen, Gracell's Senior Vice President, Head of Research & Development. "Immunosuppressive tumor microenvironment is a known challenge that limits CAR-T cell proliferation and persistence, and, ultimately, its effectiveness against solid tumors. We believe our research to be presented at SITC demonstrates SMART CART's improved resistance to TME and superior *in vitro* and *in vivo* preclinical efficacy. We look forward to advancing the clinical IIT evaluating SMART CART GC506 for the treatment of Claudin 18.2 positive tumors, building upon the success we have seen with Gracell's work in hematologic cancers."

SMART CART is Gracell's next generation CAR-T technology against solid tumors, designed to enhance CAR-T cell proliferation and persistence in suppressive TME, as well as duration of tumor killing. Immunosuppressive TME presents a major barrier to the efficacy of CAR-T in solid tumors. Research has shown that transforming growth factor- β (TGF- β) is a major mediator of T cell suppression in TME. To combat the suppressive TME, Gracell designed the proprietary switch receptor, SMART CART, to block the inhibitory TGF- β signal and convert it to a supportive signaling by combining with a stimulatory molecule for CAR-T functionality enhancement.

In the preclinical studies, SMART CART cells demonstrated enhanced resistance to TGF- β -mediated apoptosis and exhaustion. Upon repeated challenges of tumor cells, SMART CART cells showed more potent and durable tumor-specific lysis than the conventional CAR-T both *in vitro* and *in vivo* in the presence of TGF- β . Especially in mouse models, SMART CART exhibited better killing activities in tumor re-challenge studies and high tumor burden studies, compared with conventional CAR-T. Additional preclinical data will be presented at the poster presentation.

Poster presentation details are as follows:

- **Abstract title:** *SMART CAR-T cells resist tumor immunosuppressive microenvironment with enhanced efficacy against solid tumors*
- **Abstract number:** 248
- **Abstract category:** Cellular Therapies – Chimeric Antigen Receptors
- **Poster hall time:** Saturday, Nov. 4, 9:00 AM - 8:30 PM PT

Additional information about this year's SITC Annual Meeting is available [here](#).

* SMART CART™ — *Suppressive Molecule Activated and Rejuvenated T cell*

About SMART CART™

Suppressive Molecule Activated and Rejuvenated T cells (SMART CART™) is Gracell's proprietary technology module designed to further strengthen the functionality of CAR-T cells and aims to overcome tumor microenvironment (TME). SMART CART™ includes altered expression of the receptor and signaling mechanism of an inhibitory TME molecule, transforming growth factor- β (TGF- β), to enhance expansion and persistence and to reduce the exhaustion of CAR-T cells. This design reverses and turns immunosuppressive signals of TME into stimulatory reactions of CAR-T cells. SMART CART™ technology can be applied to many targets for the treatment of solid tumors.

About Gracell

Gracell Biotechnologies Inc. ("Gracell") is a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies for the treatment of cancers and autoimmune diseases. Leveraging its innovative 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 and autoimmune diseases. The lead candidate BCMA/CD19 dual-targeting FasTCAR-T GC012F is currently being evaluated in clinical studies for the treatment of multiple myeloma, B-NHL and systemic lupus erythematosus (SLE). For more information on Gracell, please visit www.gracellbio.com. Follow @GracellBio on [LinkedIn](#).

Cautionary Notes 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," "look forward to," "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 U.S. Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof. Gracell specifically disclaims any obligation to update any forward-looking statement, whether due to 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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