PRESS RELEASE

Gracell Biotechnologies Doses First Patients in First-in-Human Clinical Trial Evaluating GC012F, its Dual-Targeting FasTCAR-T Therapy, in B-Cell Non-Hodgkin's Lymphoma

Candidate dual-targeting B cell maturation antigen (BCMA) and CD19 expands Gracell's FasTCAR autologous, next-day manufacturing CAR-T platform

SUZHOU, China and PALO ALTO, Calif., Feb. 17, 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 that it has dosed multiple patients in a clinical trial evaluating GC012F, the Company's autologous CAR-T therapeutic candidate dual-targeting B cell maturation antigen (BCMA) and CD19 in B-cell non-Hodgkin's lymphoma (B-NHL). NHL is the fifth most common cancer in the U.S.[1]

The Phase 1 investigator-initiated trial (IIT), being conducted in China, is a first-in-human study evaluating FasTCAR-enabled BCMA/CD19 dual-targeting GC012F for the treatment of relapsed or refractory (r/r) B-NHL. GC012F is the first BCMA/CD19 dual-targeting CAR-T in human trials for B-NHL. Most B-NHL cells express CD19, and data also suggest that 39% to 97% clinical samples of NHL cells also express BCMA. [2] [3] [4] By simultaneously targeting BCMA and CD19, GC012F is designed to improve efficacy outcome in r/r B-NHL patients.

GC012F, developed using Gracell's proprietary FasTCAR platform which enables next-day manufacturing, is currently also being evaluated in IIT studies in China including relapsed/refractory multiple myeloma. In November 2021, GC012F was granted Orphan Drug Designation by the U.S. Food and Drug Administration.

"Dual-targeting CD19 and BCMA represents an innovative approach for the treatment of B-NHL. This study of GC012F for r/r B-NHL marks an important step in the product candidate's development to expand to additional indications and we look forward to confirming its potential to treat B-NHL, an indication for which patients are in need of additional treatment options," said Dr. Martina A. Sersch, Chief Medical Officer of Gracell. "We are confident that this study will further validate GC012F, our FasTCAR platform and our dual-CAR technology."

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3775637/
[2] Blood Cancer Journal (2020) 10:73
[3] Blood. 2017;130:2755.
[4] Hum Gene Ther. 2018; 29(5): 585.

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

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, increasing the accessibility of cell therapies for cancer patients.

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.

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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