

PRESS RELEASE



Gracell Biotechnologies Announces Enrollment of First Patient in Registrational Phase 1/2 Clinical Study for GC007g, an Allogeneic CAR-T Cell Therapy for the Treatment of Relapsed or Refractory B-ALL

SUZHOU and SHANGHAI, China, March 31, 2021 — 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, announced that they have enrolled the first patient in their pivotal Phase 1/2 clinical study of GC007g, an allogeneic donor-derived anti-CD19 chimeric antigen receptor (CAR)-T cell therapy for the treatment of B-cell acute lymphoblastic leukemia (B-ALL).

GC007g is an allogeneic HLA (human leukocyte antigen)-matched donor-derived CAR-T therapy. Gracell obtained IND approval for GC007g for the treatment of B-ALL from China’s National Medical Products Administration (NMPA) and the approval for the pivotal Phase 1/2 clinical study in December 2020. The open-label, single-arm Phase 1/2 study is evaluating the safety and efficacy of GC007g in r/r B-ALL patients.

“We are thrilled to announce the enrollment of the first patient into our registrational Phase 1/2 trial for the allogeneic donor-derived CD19-targeted CAR-T therapy, GC007g, for the treatment of patients with B-ALL,” said Dr. Martina Sersch, M.D., Chief Medical Officer of Gracell. “GC007g is a unique treatment approach for B-ALL patients who relapse after allogeneic stem cell transplantation and are not eligible for standard-of-care. With Gracell’s innovative portfolio, we are excited to bring novel CAR-T therapies to more patients with high unmet medical need.”

About GC007g

GC007g is a donor-derived CD19-directed allogeneic CAR-T cell therapy that has been studied for the treatment of r/r B-ALL in a completed investigator-initiated Phase 1 trial in China, where CAR-T cells were manufactured using T cells from an HLA-matched healthy donor.

About B-ALL

B-ALL, a major form of acute lymphoblastic leukemia (ALL), is one of the most common forms of cancer in children between the ages of two and five and adults over the age of 50.¹ In 2015, ALL affected around 837,000 people globally and resulted in 110,000 deaths worldwide.² It is also the most common cause of cancer and death from cancer among children.

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.

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: the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all, and other factors discussed in the "Risk Factors" section of the final prospectus filed 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 <https://www.cancer.org/cancer/acute-lymphocytic-leukemia/about/key-statistics.html>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055577/>