

PRESS RELEASE



China NMPA Grants Approval for the 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, January 13, 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, has been granted approval for a pivotal seamless Phase 1/2 clinical trial for 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), by China's National Medical Products Administration (NMPA) on December 24, 2020. The seamless Phase 1/2 pivotal clinical trial of GC007g will enable Gracell to potentially substantially accelerate the clinical development of GC007g in China.

GC007g is an allogeneic CAR-T therapy under development for the treatment of a subset of B-ALL patients who relapsed after receiving an allogeneic transplant. The allogeneic therapy is derived from human leukocyte antigen (HLA)-matched donor T cells. This allogeneic approach has the potential to resolve the T cell fitness issue associated with autologous CAR-T cell therapies. The donor-derived CAR-T cell therapy, GC007g, is designed for relapsed/refractory B-ALL patients who may not be eligible for autologous CAR-T therapy due to poor cell fitness, infections, and other conditions.

"The approval of the pivotal study for GC007g is an exciting milestone for the program, and more importantly, the approval of the new study design by the Chinese regulatory agency expedites the process of delivering a potential new treatment option to eligible patients in need," Dr. Martina Sersch, M.D., Chief Medical Officer of Gracell, commented. "As we continue to explore the potential of GC007g, Gracell remains focused on developing innovative cell therapies for patients with high unmet medical needs."

About GC007g

GC007g is an investigational CD19-targeted CAR-T cell therapy, where HLA-matched donors' T cells were employed to be redirected to eradicate CD19 positive leukemia cells.

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

¹ <https://www.cancer.org/cancer/acute-lymphocytic-leukemia/about/key-statistics.html>

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

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 preliminary 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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