

PRESS RELEASE



Gracell Biotechnologies Receives IND Approval from China NMPA for GC019F, a FasTCAR-Enabled CAR-T Therapy for the Treatment of Relapsed or Refractory Adult B-ALL

SUZHOU and SHANGHAI, China, January 19, 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, today announced that the National Medical Products Administration (NMPA) in China has approved an investigational new drug (IND) application to study GC019F, a FasTCAR-enabled chimeric antigen receptor (CAR)-T therapy in patients with relapsed or refractory adult B-cell acute lymphoblastic leukemia (B-ALL).

GC019F is an autologous CAR-T therapy currently in development for adult B-ALL patients who are relapsed from or refractory to prior therapies. With the therapy, a patient's own T cells are genetically modified to express CD19-specific CAR. GC019F is manufactured on Gracell's FasTCAR technology platform, which significantly reduces manufacturing time from an industry norm of two to six weeks down to 22 to 36 hours.

"This marks the first IND approval for a product candidate manufactured on Gracell's FasTCAR platform and sets an important milestone for furthering therapies manufactured on this platform. We are excited to bring this new therapy to adult B-ALL patients, who - once relapsed from or refractory to therapy - remain a high unmet medical need with limited treatment options in China," commented Dr. Martina Sersch, M.D., Ph.D., Chief Medical Officer of Gracell.

About GC019F

GC019F is an autologous investigational CD19-targeted CAR-T cell therapy, directed to eradicate CD19 positive leukemia cells.

About FasTCAR

FasTCAR-manufactured CAR-T cells 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 (22 to 36 hours), 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 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

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

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 Note 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 further advancement of, and anticipated clinical development and regulatory milestones of GC019F. 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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² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055577/>