

## PRESS RELEASE



### **Gracell Announces China NMPA Acceptance of Investigational New Drug Application for GC007g Cell Therapy for CD19 Positive Relapsed or Refractory B-cell Acute Lymphoblastic Leukemia**

SUZHOU and SHANGHAI, China, Apr.3<sup>rd</sup> 2020 /PRNewswire/ -- Gracell Biotechnologies Co., Ltd. ("Gracell"), a clinical-stage immune cell & gene therapy company, is pleased to announce that China National Medical Products Administration (NMPA) has accepted Gracell's Investigational New Drug (IND) application for GC007g, a donor-derived anti-CD19 chimeric antigen receptor (CAR-T) cell therapy.

GC007g is an allogenic CAR-T therapy under development for B-ALL patients who relapsed or refractory from prior treatment. The therapy utilizes healthy T cells from human leukocyte antigens (HLA) matching donors, with potentially better T cell fitness, and possibly higher efficacy compared to the use of patient's own T cells. The company plans to initiate a phase 1 clinical study in patients with CD19 positive relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) in Q2, 2020.

"The IND approval for GC007g marks a significant milestone for Gracell." said Dr. William CAO, founder and CEO of Gracell, "We are delighted that this first-of-its-kind CAR-T program will soon be evaluated in IND approved clinical trials. We expect donor-derived CAR-T therapy, GC007g may become a good alternative solution to the r/r B-ALL patients who may not be eligible for autologous CAR-T therapy due to infections and other conditions, to those who do not respond to autologous CAR-T therapy, or to those whose CAR-T cells fail to be manufactured successfully".

#### **About GC007g**

GC007g is an investigational CD19-targeted CAR-T cell therapy, where HLA matching donors' T cells were employed to 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<sup>1</sup>. In 2015, ALL affected around 837,000 people globally and resulted in 110,000 deaths worldwide<sup>2</sup>. It is also the most common cause of cancer and death from cancer among children. First onset ALL is typically treated with long term chemotherapy. In case of relapsed or refractory disease immunotherapy monoclonal antibodies may be an option in certain subtypes while CART therapy may be an option for patients 25 and younger.

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

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

**About Gracell**

Gracell Biotechnologies Co., Ltd. ("Gracell") is a clinical-stage biotech company, committed to developing highly reliable and affordable cell gene therapies for cancer. Gracell is dedicated to resolving the remaining challenges in CAR-T, such as high production costs, lengthy manufacturing process, lack of off-the-shelf products, and inefficacy against solid tumors. Led by a group of world-class scientists, Gracell is advancing *FastCAR*<sup>™</sup>, *TruUCAR*<sup>™</sup> (off-the-shelf CAR), Dual CAR and Enhanced CAR-T cell therapies for leukemia, lymphoma, myeloma, and solid tumors.

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