PRESS RELEASE

Gracell Initiates Investigational Study of the Technological Breakthrough *TruUCAR*™ Therapy for Relapsed or Refractory T-cell Malignancies

SUZHOU and SHANGHAI, China, January 7, 2019 /PRNewswire/ -- Gracell Biotechnologies Co., Ltd. ("Gracell"), a clinical-stage immune cell therapy company, today announced the initiation of an investigational study of GC027, the first product candidate developed using *TruUCAR*™ to treat relapsed or refractory (R/R) T-cell malignancies.

T-cell acute lymphoblastic leukemia or T-ALL is an aggressive form of ALL, which affects white blood cells and the bone marrows ability to generate healthy blood cells. About 15-20% of people with ALL have T-ALL. While T-ALL is treatable by chemotherapy and stem cell transplant, around 75% of patients will relapse within two years[1]. T-cell lymphoblastic lymphoma (T-LBL) is another devastating T-cell malignancies. For patients who develop R/R T-ALL or T-LBL, there are few options for treatment.

Autologus CAR-T therapies rely on patients' own T cells, which have been affected by prior therapies; thus, cell quality as well as efficacy remains questionable. Allogenic CAR-T therapies made of healthy donors' T cells would be characterized as being of consistently good quality with the potential to improve efficacy. Unlike autologous CAR-T cells, allogeneic CAR-T cells can be made as off-the-shelf product which means patients do not have to wait for lengthy production time. Furthermore, the cost of production can be significantly lower. Allogenic CAR-T therapies also provide a vital treatment option for patients with viral infections and/or other conditions prohibiting access to autologous cell therapies.

TruUCAR™ based GC027 is designed to meet the above unmet needs. Its cells are made of T cells from healthy donors, genetically edited and inserted with chimeric antigen receptor (CAR) *ex vivo*, which can specifically bind to and eliminate target cells - T malignant cells. Different from industry leaders' off-the-shelf CAR-T design, Gracell's proprietary and patented *TruUCAR*™ technology requires no co-administration of anti-CD52, a cytotoxic agent for ablating cancerous cells while inducing long term immune depletion in the patient. Instead, GC027 utilizes CRISPR genome editing strategy that is expected to avoid graft-versus-host disease (GvHD) as well as graft rejection caused by the patients' immune system.

The prudent preclinical studies provide substantial evidence to trigger GC027 moving into a non-IND (investigational new drug) clinical trial to evaluate the safety, pharmacokinetics and pharmacodynamics of GC027 therapy in patients suffering from relapsed and refractory T lymphocyte malignancies.

"*TruUCAR*™ is another technological breakthrough developed by Gracell following the recent announcement of *FasTCAR*™ technology and products. It enables producing off-the-shelf CAR-T cells from

healthy MHC (major histocompatibility complex) mismatched donors with a large number of doses readily to be dispatched to patients in need.

“Launch of the investigational GC027 study as the first-of-its-kind therapy marks another significant milestone for Gracell,” said Dr. William CAO, Founder and CEO of Gracell. “Once the concept is well-proved with solid evidence for safety and efficacy, we will immediately deploy development of a series of *TruUCAR*™ products for other medical unmet needs, including B cell malignancies.”

About GC027

GC027 is an investigational, off-the-shelf CAR-T cell therapy for T cell malignancies, derived from healthy donors. The use of healthy donor’s cells are preferential to a patient’s own to potentially improve efficacy, reduce production time and cost of goods.

About T-ALL

T lymphoblastic leukemia (T-ALL) is an aggressive form of T cell malignancies, with a diffuse invasion of bone marrow and peripheral blood. In 2015, ALL affected around 876,000 people globally and resulted in 110,000 deaths worldwide. T-ALL compromises about 15%-20% children and adults[1]. Current standard therapies for T-ALL are chemotherapies and stem cell transplantation. A large portion of these patients will experience relapse within two years following treatment by conventional therapies.

About T-LBL

T lymphoblastic lymphoma (T-LBL) is an aggressive form of T cell malignancies, with rare lymphoproliferative neoplasm of mature T cells caused by infection with the retrovirus human T lymphotropic virus. T-LBL compromises about 2% of adult NHL and 30% of pediatric NHL patients[2]. Five-year overall survival is only 14% in adults. Although first-line treatment using cytotoxic combination chemotherapy can achieve 70% ORR, nearly 90% of patients relapse, often within months of completing chemotherapy.

About Gracell

Gracell Biotechnologies Co., Ltd. ("Gracell") is a clinical-stage biopharma 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*™, *TruUCAR*™ (off-the-shelf CAR), Dual CAR and Enhanced CAR-T cell therapies for leukemia, lymphoma, myeloma, and solid tumors.

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[1] Pediatric hematologic Malignancies: T-cell acute lymphoblastic Leukemia, Hematology 2016
[2] Clinical Review: Adult T-cell Leukemia/lymphoma, Journal of Oncology Practice 2017