PRESS RELEASE

Gracell Reports Data of First-in-human Clinical Trial for Universal *TruUCAR*™ GC027 in Relapsed or Refractory T-cell Acute Lymphoblastic Leukemia at the AACR Virtual Annual Meeting

SUZHOU and SHANGHAI, China, Apr.28, 2020 /PRNewswire/ — Gracell Biotechnologies Co., Ltd. ("Gracell"), a clinical-stage immune cell and gene therapy company, has announced data of its first-in-human clinical trial for Universal *TruUCAR*™ GC027 in relapsed or refractory (R/R) T-cell acute lymphoblastic leukemia (T-ALL) patients. The data was presented in the Adoptive Cell Transfer Therapy section during the American Association for Cancer Research (AACR) Virtual Annual Meeting held on April 28.

T-ALL, a form of acute lymphoblastic leukemia, consisting of 20-25% of adult ALL, and 12-15% of pediatric ALL, represents a hard-to-treat disease with a high unmet clinical need.[1] Outcome of relapsed and refractory T-ALL remains poor, with very limited treatment options available. Most T-ALL patients relapse within two years after multi-agent chemotherapy regimens. The study of *TruUCAR*™ GC027 in relapsed and refractory T-ALL reports early efficacy outcomes of five patients treated in this area of high unmet medical need.

The clinical investigator initial trial (IIT) intends to evaluate safety and efficacy of *TruUCAR*™ GC027, the first-in-human, universal CAR-T therapy for R/R T-ALL. As of February, the study enrolled a total of five patients with R/R T-ALL, with median prior lines of therapy 5 (range 1-9). Baseline bone marrow tumor burden was 38.2% (range 4-80.2). All patients received a single infusion of *TruUCAR*™ GC027 in one of three dose levels: 0.6*10^7cells/kg, 1.0*10^7cells/kg or 1.5*10^7cells/kg. Notably, these patients were not HLA matched, and no one accepted post-infusion hematopoietic stem cell transplantation (HSCT).

Treatment efficacy was assessed in five patients with 28 days of follow-up, of which:

- Five (100%) achieved a complete remission with or without complete blood count recovery (CR/CRi);
- Four (80%) achieved minimum residual disease negative complete remission (MRD-CR).

All five patients tolerated the single infusion of *TruUCAR*™ GC027 with no neurotoxicity events or acute graft-versus-host disease (aGvHD) observed. Cytokine release syndrome (CRS) presented in all patients at any grade.

[1] Pediatric hematologic Malignancies: T-cell acute lymphoblastic Leukemia, Hematology 2016

“We are delighted to report the outcome on the first five patients treated with *TruUCAR*™ GC027. These promising preliminary results are encouraging and warrant further evaluation of the therapy in this area of high unmet clinical need.” said Dr. Martina Sersch, CMO of Gracell.

About *TruUCAR*™

TruUCAR™ is Gracell’s proprietary and patented platform technology, with selected genes being edited to avoid GvHD and immune rejection without using strong immunosuppressive drugs. In addition to T-ALL antigen, the platform technology can also be implemented for other targets of hematological malignancies.

About GC027

GC027 is an investigational, off-the-shelf CAR-T cell therapy, redirected to CD7 for the treatment of T cell malignancies. GC027 was manufactured from T cells of human leukocyte antigen (HLA) unmatched healthy donors using *TruUCAR*™ technology, which is expected to improve efficacy and reduce production time, available for off-the-shelf use in a timely manner.

About T-ALL

T - Lymphoblastic Leukemia (T-ALL) is an aggressive form of acute lymphoblastic leukemia, with a diffuse invasion of bone marrow and peripheral blood. In 2015, T-ALL affected around 876,000 people globally and resulted in 110,000 deaths worldwide. T-ALL compromises about 15%-20% of all children and adult acute lymphoblastic leukemia[2]. Current standard of care therapies for T-ALL are chemotherapy and stem cell transplantation. 40-50% of patients will experience relapse within two years following front line therapy with limited treatment options available[3][4]. Treatment of relapsed and refractory T-ALL remains a high unmet medical need.

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*™, *TruUCAR*™ (off-the-shelf CAR), Dual CAR and Enhanced CAR-T cell therapies for leukemia, lymphoma, myeloma, and solid tumors.

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[2] Pediatric hematologic Malignancies: T-cell acute lymphoblastic Leukemia, Hematology 2016
[3] Progress and innovations in the management – JAMA Oncol 2018
[4] Defining the course and prognosis of adults with acute lymphoblastic leukemia, Cancer 2010