PRESS RELEASE

Gracell Announces Interim Readout of Investigation for First-in-class FasT CAR-19 in patients with Relapsed or Refractory B-cell Acute Lymphoblastic Leukemia and Extension in Use of FasT CAR to Other Immune Cell Programs

- The study shows a high response rate, with 23 of 24 treated patients achieving complete remission and 21 of 24 treated patients achieving undetectable minimal residual disease on 28 days of follow-up
- All 26 patient samples were manufactured overnight with 100% success
- FasT CAR-19 is expected to be a best-in-class therapy for relapsed or refractory B-ALL
- FasT CAR technology is applicable in other immune cell programs, including CAR-T cells redirected to target bispecific antigens, including CD19/22, and BCMA/antigen X
- The non-clinical study demonstrated Dual CAR-T cells (GC012F and GC022F) with FasT CAR bioprocess poses similar features to FasT CAR-19 (GC007F)

SUZHOU and SHANGHAI, China, 11 September 2019 -- Gracell Biotechnologies Co., Ltd. ("Gracell"), a clinical-stage immune cell therapy company, today announced a positive continued clinical readout of a multi-center pilot study designed to evaluate the safety and efficacy of Gracell's first-in-class FasT CAR-19 (GC007F) investigational cell gene therapy. The results were announced during the CAR-TCR Summit held from 10-13 September in Boston.

At present, anti-CD19 CAR-T bioprocessing takes on average two weeks to manufacture and seven days to pass quality testings. However, with Gracell's FasT CAR solution, customized treatments which genetically modifies patient's T-cells to express CD19-specific chimeric antigen receptor (CAR), preparation time can be cut to one day, with a manufacturing success rate of 26/26 (100%) without patient loss. FasT CAR technology can also be utilized on other immune cell programs, such as the treatment of multiple myeloma (MM) and Non-Hodgkin Lymphoma (NHL). With these advantages, FasT CAR-19 is highly cost-effective and has considerable potential to establish a new standard in CAR-T treatment for r/r B-ALL.

The multi-center investigational study enrolled 26 adolescent and adult patients aged from 14 to 70 years, with relapsed or refractory B-ALL, and had failed to respond to multiple prior lines of therapy. As of Sep. 4, all patients received a single infusion of FasT CAR-19 following lymphoid depleting chemotherapy. FasT CAR-19 was administered at three dose levels from low to high, equivalent to 1/30-1/10 of the conventional CAR-T therapy dose for B-ALL, respectively.

The treatment efficacy was assessed in 24 treated patients over 28 days of follow-up, of which:

- 23 (95.8%) achieved complete remission with or without complete blood count recovery (CR/CRi);

- 21 (87.5%) achieved undetectable minimal residual disease (uMRD) (< 10^{-4} detectable leukemic cells in bone marrow).

During the over three month-durable remission period, FasT CAR-19 demonstrated a good level of persistence. In terms of safety, all 26 patients well tolerated the single infusion of FasT CAR-19 at different dose levels. The most common safety concerns were cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) where mild to moderate side effects were observed.

In comparison to the high dose group, patients administered low to middle dose levels experienced mild adverse events. Across 20 patients in the low to mid doses group, only 2 (10%) Grade 3 CRS and 2 (10%) manageable Grade 3 ICANS were reported; while in the 6 patients of the high dose group, there were 5 (83.3%) Grade 3 CRS and 1 (16.7%) Grade 1-2 ICANS, indicating a dose-limiting toxicity.

Taking FasT CAR-T Further: GC012F and GC022F

CAR-T immunotherapy uses patients' own immune cells to treat disease. In this form of therapy, immune cells are collected from a patient's blood; engineered in a laboratory to create a chimeric antigen receptor cells (CAR) that target cancer cells and then reinfused back into the patient. However, such therapy is time-consuming, highly personalized. Furthermore, it can only target a single tumor antigen, which limits efficacy.

To combat this, treatments containing two separate CARs and dual transduction (GC012 targeting BCMA and antigen X, and GC022 targeting CD19 and CD22), which were expected to have a higher safety profile and ability to control and prevent relapse compared to single CAR-T cells were developed. As both programs (GC012F and GC022F) hold similar characteristics to GC007F, there is potential to enhance the therapies through the FasT CAR platform, enabling GC012F and GC022F to perform better than the conventionally manufactured dual CAR-T cells.

The results from *in vitro* studies have already shown that GC012F and GC022F provide a higher portion of centry memory T cells with less exhaustion, higher proliferation capacity, and killing ability similar to conventional CAR-T cells at the same cell basis. While *in vivo* studies, show lower dose poses higher potency, greater efficiency and better ability to eradicate tumor cells.

"We are very excited to see that the patients with refractory or relapsed B-ALL in this study gained substantial clinical benefit from FasT CAR-19" said CEO Dr. William CAO. "Dual CAR-T cells manufactured using the FasT CAR platform has the potential to offer more clinical benefits. The next stage will be to unlock these benefits with first-in-human trials."

About FasT CAR-19

FasT CAR-19, or GC007F, is an investigational CD19-targeted CAR-T cell therapy for adolescent and adult patients with refractory or relapsed B-ALL, as well as aggressive non-Hodgkin lymphoma. Thanks to Gracell's patented FasT CAR technology, the bioprocessing of GC007F has been significantly reduced to 24 hours with substantially lower cost. The younger and less exhausted T cell phenotype exhibited superior proliferation capabilities, potency, and extensive bone marrow migration making GC007F a potential best-in-class therapy for refractory or relapsed B-ALL.

About ALL

Acute lymphoblastic leukemia (ALL), although rare, 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 876,000 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. ALL is typically treated initially with chemotherapy aimed at bringing about remission. This is then followed by further chemotherapy carried out over several years.

About MM

Multiple myeloma (MM) is a cancer that forms in a type of white blood cell known as a plasma cell. Plasma cells help fight infection by making antibodies. MM causes cancer cells to accumulate in the bone marrow, where they crowd out healthy blood cells. Rather than producing antibodies, the cancer cells produce abnormal proteins which cause complications (myeloma cells).

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 FasT CAR, 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] https://www.cancer.org/cancer/acute-lymphocytic-leukemia/about/key-statistics.html
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055577/