PRESS RELEASE

Gracell Data on Multi-center Investigation of FasT CAR-19 Therapy Shows Positive First Impact in Patients with Relapsed or Refractory B-cell Acute Lymphoblastic Leukemia

- Preliminary data shows a high response rate, with 16 of 16 patients achieving complete remission and 14 of 16 patients achieving undetectable minimal residual disease with mild side effect observed
- FasT CAR-19 (GC007F) can be manufactured overnight with 100% success
- FasT CAR-19 is expected to be a best-in-class therapy for refractory or relapsed B-ALL.

SUZHOU and SHANGHAI, China, June 20, 2019 /PRNewswire/ -- Gracell Biotechnologies Co., Ltd. ("Gracell"), a clinical-stage cellular immunotherapy company, today announced preliminary results of a multi-center pilot study designed for evaluating the safety and efficacy of Gracell's patented FasT CAR-19 (GC007F) investigational cell gene therapy. The customized treatment which genetically modifies patient's T-cells to express CD19-specific chimeric antigen receptor (CAR), showed a clinically meaningful and positive result in the treatment of B-cell acute lymphoblastic leukemia (B-ALL). The results of the study were announced during the CAR-TCR Summit Asia, held June 18-20, 2019 in Shanghai.

B-ALL is a sub-type of ALL, a cancer of the lymphoid line of blood cells. For a vast number of patients, B-ALL can be treated by chemotherapy and stem cell transplant. However, for the many patients who develop refractory or relapsed (r/r) B-ALL, significant complications in treatment remain. With characteristically low life expectancy, r/r B-ALL is one of the most devasting forms of malignancies. Anti-CD19 CAR-T products have been developed specifically for these late-stage patients.

Currently approved anti-CD19 CAR-T bioprocessing takes on average two weeks to manufacture and seven days to pass quality test. With Gracell's FasT CAR solution, preparation time can be cut to 24 hours, significantly reducing production cost and waiting time. In addition, FasT CAR can be administered vein-to-vein (time from when cells are extracted to when they are infused back into the patient) within seven days after leukapheresis, providing substantial meaning and significant benefitto physicians and patients.

With a manufacturing success rate of 19/19 (100%) without patient loss, FasT CAR-19 cells are considered much more potent and durable in comparison to currently available alternatives. 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 19 adolescent and adult patients aged from 14 to 70 years, who suffered from refractory or relapsed B-ALL and had failed to respond to multiple prior lines of therapy. As of June 12, all patients received a single infusion of FasT CAR-19 following lymphodepleting chemotherapy. FasT CAR-19 was administered at three dose levels from low to high, equivalent to 1/30-1/10 of the standard CAR-T therapy dose, respectively.

The treatment efficacy was assessed in 16 patients, of which:

- 16 (100%) achieved complete remission with or without complete blood count recovery (CR/CRi);
- 14 (87%) achieved undetectable minimal residual disease (uMRD) (< 10^{-4} detectable leukemic cells in bone marrow);
- 15 (94%) experienced an ongoing response by June 12. Notably, one adolescent patient achieved CR and uMRD after 28 days of regular follow-up treatment, turned MRD positive at week 12, and converted back to uMRD again at week 20 with the ongoing response status remaining up to June 12.

During the over six month-durable remission period, FasT CAR-19 demonstrated a good level of persistence. In terms of safety, all 19 patients tolerated the single infusion of FasT CAR-19 at different dose levels, with no dose-limiting toxicities observed. 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 14 patients in the low to mid doses group, only 2 (14%) Grade 3 CRS and 1 (7%) manageable Grade 3 ICANS were reported; while in the 4 patients of the high dose group, there were 3 (75%) Grade 3 CRS and 2 (50%) Grade 1-2 ICANS.

“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. “Although the potential of FasT CAR technology is yet to be unlocked, the results of this study have enhanced our confidence to move on with dose expansion studies and to apply FasT CAR to products for various indications, including multiple myeloma and non-Hodgkin lymphoma. We are eager to see Gracell’s highly efficacious, but affordable FasT CAR-T therapies benefit patients globally.”

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, 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

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

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 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, UCAR[3], Dual CAR and Enhanced CAR platform technologies for leukemia, lymphoma, myeloma, and solid tumors.

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[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055577/