PRESS RELEASE

Gracell Announces Five Presentations at the Annual Meeting of American Society of Hematology (ASH)

SUZHOU and SHANGHAI, China, 15 November 2019 /PRNewswire/ -- Gracell Biotechnologies Co., Ltd. ("Gracell"), a clinical-stage immune cell therapy company, today announced five presentations to be delivered at the upcoming American Society of Hematology (ASH) Annual Meeting in Orlando, Florida, held from December 7-10.

The presentations centre on Gracell’s breakthrough FasTCAR™ technology, and other two platform technology in four product categories used in the treatment of hematological malignancies, each with well-defined objectives, including:

- FasT CAR-19 (GC007F)
- Dual CAR-19-22 (GC022)
- Dual CAR-BCMA-19 (GC012)
- Donor CAR-19 (GC007G)

The four product candidates are currently being studied in ongoing phase I clinical trials conducted by Gracell, Hebei Yanda Lu Daopei Hospital, and Xinqiao Hospital of AMU, and six other hospitals nationwide in China.

“These clinical studies demonstrated Gracell’s product development strategy and strong capabilities to bring multiple novel therapies through clinical investigations,” said Dr. William CAO, CEO of Gracell. “These invaluable data provides guidance for and enhance our confidence in pipeline selection.”

Oral presentations:

A Feasibility and Safety Study of a New CD19-Directed Fast CAR-T Therapy for Refractory and Relapsed B cell Acute Lymphoblastic Leukemia
Abstract #825
Session Name: 612. Acute Lymphoblastic Leukemia: Clinical Studies: Therapeutics Strategies
Presenter: Peihua Lu, M.D., Hebei Yanda Lu Daopei Hospital
Location: Orange County Convention Center, Tangerine 1 (WF1), Level 2
Time: 5:00 pm, Monday, December 9, 2019

Anti-CD19/CD22 Dual CAR-T Therapy for Refractory and Relapsed B-Cell Acute Lymphoblastic Leukemia
Abstract #284
Session Name: 612. Acute Lymphoblastic Leukemia: Clinical Studies: Novel Therapies
Presenter: Peihua Lu, M.D., Hebei Yanda Lu Daopei Hospital
Location: Orange County Convention Center, W224, Level 2
Time: 4:15pm, Saturday, December 7, 2019
Poster presentations:

CD19-Directed Fast CART Therapy for Relapsed/Refractory Acute Lymphoblastic Leukemia: From Bench to Bedside
Abstract #1340
Session Name: 614. Acute Lymphoblastic Leukemia: Therapy, excluding Transplantation: Poster I
Presenter: Cheng Zhang, M.D., Xinqiao Hospital of AMU
Location: Orange County Convention Center, Hall B, Level 2
5:30-7:30 pm, Saturday, December 7, 2019

A Bcma and CD19 Bispecific CAR-T for Relapsed and Refractory Multiple Myeloma
Abstract # 3147
Session Name: 653. Myeloma: Therapy, excluding Transplantation: Poster II
Presenter: Hua Zhang, PhD., Gracell Biotechnology Ltd., Shanghai, China
Location: Orange County Convention Center, Hall B, Level 2
6:00 PM-8:00 pm, Sunday, December 8, 2019

Role of Donor-Derived CD19.CAR-T Cells in Treating Patients That Relapsed after Allogeneic Hematopoietic Stem Cell Transplantation
Abstract #4561
Session Name: 723. Clinical Allogeneic and Autologous Transplantation: Late Complications and Approaches to Disease Recurrence: Poster III
Presenter: Cheng Zhang, M.D., Xinqiao Hospital of AMU
Location: Orange County Convention Center, Hall B, Level 2
6:00-8:00 pm, Monday, December 9, 2019

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 FastTCAR™ technology, the bioprocessing time for GC007F has been significantly reduced from two weeks to 24 hours with substantially lower cost. The improved CAR-T cell fitness resulted in superior proliferation capabilities, potency, and extensive bone marrow migration making GC007F a potential best-in-class therapy for refractory or relapsed B-ALL.

About Dual CAR-19-22
Dual CAR-19-22, or GC022, is an investigational CAR-T cell therapy redirected to target CD19 and CD22, in treating patients with CD19+, or/and CD22+ relapsed/refractory B-ALL. A low toxicity with dose-dependent high CR rate including patients who previously treated with CD19 CAR-T cells were observed.

About Dual CAR-BCMA-19
Dual CAR-BCMA-19, or GC012, is an investigational CAR-T cell therapy redirected to target BCMA and CD19, in treating patients with BCMA+, or/and CD19+ relapsed/refractory multiple myeloma. Previous research shows CD19 could express on the myeloma progenitor cells, while BCMA is a well validated target for MM.

About Donor CAR-19
Donor CAR-19, or GC007G, is an investigational CD19 targeted CAR-T cell therapy manufactured in use of donor’s lymphocytes. The objective of this study is to further investigate and better understand the safety and efficacy of donor derived CAR-T cells in treatment of relapsed and refractory B-ALL patients.

About B-ALL
B-ALL is a sub-type of 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. In 2015, ALL affected around 876,000 people globally and resulted in 110,000 deaths worldwide. 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
Myeloma begins when a plasma cell becomes abnormal. The abnormal cell divides to make copies of itself. These abnormal plasma cells are called myeloma cells. In time, myeloma cells collect in the bone marrow. They may damage the solid part of the bone. When myeloma cells collect in several of your bones, the disease is called "multiple myeloma." This disease may also harm other tissues and organs, such as the kidneys. Myeloma cells make antibodies called M proteins and other proteins. These proteins can collect in the blood, urine, and organs.

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