PRESS RELEASE

Gracell Biotechnologies Announces Presentation of First-in-Human Data of GC012F a First-in-Class FasTCAR-enabled Dual-targeting BCMA/CD19 CAR-T Cell Therapy for Patients with Relapsed or Refractory Multiple Myeloma at 2020 ASH Annual Meeting

SUZHOU and SHANGHAI, China, Dec. 5, 2020 -- Gracell Biotechnologies Inc. ("Gracell"), a global clinical-stage biopharmaceutical company dedicated to developing highly efficacious and affordable cell therapies for the treatment of cancer, today announced an interim readout to evaluate the safety and efficacy of its potential first-in-class GC012F FasTCAR-enabled dual-targeting BCMA/CD19 cell therapy in patients with relapsed or refractory multiple myeloma (R/R MM). The data were presented by Dr. Weijun Fu, Professor of Hematology, Director at Shanghai Changzheng Hospital, as an oral presentation at the American Society of Hematology's (ASH) 2020 Annual Meeting.

GC012F, a dual BCMA/CD19 targeting CAR-T cell therapy developed on Gracell's FasTCAR platform - which enables next-day manufacturing - was evaluated in an investigator-initiated Phase 1 trial. As of July 17th, the study enrolled sixteen patients at three dose levels with the highest dose level of 3x10^5 cells per kg. After three days of a standard lymphodepleting regimen, patients received GC012F as a single infusion over 30 minutes.

- Early Overall Response Rate (ORR) showed a promising 93.7% with all responses being VGPR or better - showing fast, deep and durable responses in all dose levels
- 100% of the patients treated at the highest dose level (n=6) obtained MRD negative sCR which was maintained through the landmark analysis of six months (n=4) at the time of data cut off

The median duration of follow-up at time of assessment was 7.3 months (range 1–10 months). Of the sixteen patients treated, 93.7% were classified as high-risk according to mSMART 3.0 guidelines, 19% had double hit R/R MM, and 31% had extramedullary disease. Patients had received a median of 5 prior lines of therapy, with 75% being refractory to last therapy and 19% being primary refractory. 94% of the patients were triple exposed to a PI, IMiD, and at least a third treatment modality, including anti-CD38 targeted therapy. 63% were penta-exposed with at least five different treatment modalities, including PI, IMiD and others. One patient with extramedullary disease obtained MRD negative result at his first bone marrow assessment at month 1, however, he was considered a non-responder based on the increasing size of the extramedullary lesion at month 1.

The safety profile of GC012F was manageable with an overall low grade of cytokine release syndrome (CRS) (87.5 % Grade 1/2, 2 patients Grade 3, no Grade 4 or 5) and a median duration of four days ranging from 1–8 days. CRS was treated with Standard of Care treatment, including tocilizumab and steroids, and resolved in all cases. No ICANS (immune effector cell-associated

neurotoxicity) was observed in any of the sixteen patients. Treatment-emergent adverse events (TEAEs) presented predominantly as cytopenias and AST increase. Lower respiratory tract infection was observed in three patients. All TEAEs were resolved with standard therapy.

“We are extremely encouraged about these early findings in sixteen patients with predominately high-risk features,” said Dr. Martina Sersch, MD, PhD, CMO of Gracell. “High-risk patients are difficult to treat successfully and to achieve longer-term remission. A 100% MRD-sCR at month six post-infusion after treatment with GC012F at the highest dose level shows promise for heavily pretreated patients who have failed or were no longer responding to standard treatment options. We are planning to expand our program globally and are looking forward to sharing updates as we advance our programs through clinical development.”

About Gracell

Gracell Biotechnologies Inc. ("Gracell") is a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies. Leveraging its pioneering FasTCAR and TruUCAR technology platforms, Gracell is developing a rich clinical-stage pipeline of multiple autologous and allogeneic product candidates with the potential to overcome major industry challenges that persist with conventional CAR-T therapies, including lengthy manufacturing time, suboptimal production quality, high therapy cost and lack of effective CAR-T therapies for solid tumors.

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