

Gracell Bio develops technology for Hematological Malignancies

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Gracell conquers effective, low cost, and high speed manufacturing of cellular gene therapeutics



Gracell Biotechnologies is an immune cell gene therapy company, headquartered in Suzhou, China, with additional locations in Shanghai and Hong Kong. Gracell recently announced that it has developed FasT CAR-T, a revolutionary platform that shortens the manufacturing time of CAR-T treatments from two weeks to one day.

FasT CAR-T also lowers manufacturing costs to a fraction of previous CAR-T therapies, while showing higher potency of CD19-directed FasT CAR-T ("CD19-F-CAR-T") in B-Cell acute lymphoblastic leukemia (B-ALL) and non-Hodgkin Lymphoma (NHL), both in vitro and in vivo.

With a first-in-human clinical study of CD19-F-CAR-T ongoing, Gracell said early clinical results show the therapy is safe and significantly more potent (20-40 times) than conventionally manufactured CAR-T agents (C-CAR-T) for treating B-ALL.

FasT CAR-T requires only one day for manufacturing (plus 7 days for releasing tests per regulatory requirement), while C-CAR-T manufacturing takes about two weeks plus 7 days for testing. Hence, FasT CAR-T reduces vein-to-vein time by an average of 12 days, which is critical for patients with rapidly progressing disease. More importantly, CD19-F-CAR-T has demonstrated superior expansion capability, with a younger and less exhausted phenotype, according to the Company.

Gracell has been developing a series of highly effective and low-cost CAR-T products, including Dual-CAR-T, Off-the-shelf CAR-T, and Enhanced-CAR-T products for treating solid tumors, two of which will be entering IND filing by the end of this year. Next year, the company plans to file INDs for three additional products.