



Gracell Biotechnologies Reports First Quarter 2021 Unaudited Financial Results and Provides Corporate Update

Reported updated long-term follow-up data for TruUCAR-enabled CD7-targeted CAR-T product candidate GC027 for the treatment of T-ALL at AACR 2021 Annual Meeting

Signed agreement with Lonza to manufacture FasTCAR-enabled product candidates in the U.S.

Completed initial public offering of ADSs for net proceeds of US\$220 million; US\$331.1 million in cash as of March 31, 2021

SUZHOU, China and PALO ALTO, Calif., May 17, 2021 (GLOBE NEWSWIRE) -- Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell"), a global clinical-stage biopharmaceutical company dedicated to discovering and developing highly efficacious and affordable cell therapies for the treatment of cancer, today reported its unaudited financial results for the first quarter and recent business highlights.

"We are thrilled to have ushered in the new year as a public company following a successful initial public offering that was supported by top-tier institutional investors," commented Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. "We have made significant advancements during the first quarter regarding our pipeline of innovative autologous and allogeneic CAR-T cell therapies. Recently, we announced dosing the first patient in the Phase 1/2 registrational study of GC007g, an allogeneic CAR-T cell therapy derived from HLA-matched donors for the treatment of r/r B-ALL. At the AACR 2021 Annual Meeting last month, we presented follow-up data on our off-the-shelf stand-alone allogeneic CAR-T cell therapy GC027 for the treatment of r/r T-ALL. With a patient maintaining minimal residual disease negative complete remission (MRD- CR) through 16.8 months, we are very encouraged by the potential of GC027 in this hard-to-treat indication."

Dr. Cao continued, "We are pleased to announce that we are expanding our leadership team with Jenny (Yajin) Ni, Ph.D., M.D., as Chief Technology Officer. Dr. Ni brings extensive experience in developing CAR-T cell therapies, including having successfully lead process development at both Pfizer and Allogene Therapeutics. We look forward to her contributions, including leading our technical operations teams including Chemistry, Manufacturing and Control (CMC) and manufacturing to ensure a smooth technology transfer to Lonza for our FasTCAR-enabled product candidate GC012F."

"We plan to build on the momentum achieved during the first quarter with several near-term catalysts expected during 2021. As we continue to ramp up clinical development efforts, we continue to expand our team in the U.S. and preparing to expand our GMP manufacturing facility in China. We also look forward to providing updates at the ASCO and EHA 2021 annual meetings on the FasTCAR-enabled BCMA/CD19 dual-targeting candidate GC012F for the treatment of r/r multiple myeloma, which has demonstrated fast, deep, and durable responses in a predominantly high-risk multiple myeloma patient population. We are excited to begin collaborating with Lonza to manufacture our FasTCAR-enabled product candidate GC012F as we work towards the U.S. IND filing in the first half of 2022. We believe the potential of our proprietary FasTCAR and TruUCAR platforms is vast, and we are working expeditiously to bring new product candidates into clinical development," Dr. Cao concluded.

First Quarter 2021 and Subsequent Highlights

GC027 for the treatment of adult relapsed/refractory T cell acute lymphoblastic leukemia (r/r T-ALL):

GC027 is a TruUCAR-enabled CD7-targeted allogeneic CAR-T cell therapy being studied in an ongoing Phase 1 IIT in China for the treatment of adult r/r T-ALL. GC027 is manufactured from T cells of non-HLA (human leukocyte antigen)-matched healthy donors.

- Updated long-term follow-up data (data cut-off as of February 4, 2021) for GC027 was presented at the 2021 American Association for Cancer Research (AACR) Annual Meeting (Press Release [April 2021](#))
 - Patients had received a median of six prior lines of therapy and received a single infusion of TruUCAR GC027 in one of three dose levels with the highest dose level at 1.5×10^7 cells/kg. Six patients (100%) treated achieved a complete remission with or without complete blood count recovery (CR/CRi) and five of the six patients (83%) achieved MRD- CR. At 6 months post treatment, three out of five patients (60%) had maintained MRD- CR. After 18.5 months of follow up for the initial patients treated, one patient continued to be MRD- CR at 16.8 months. One patient maintained MRD- CR until 9 months and one patient with primary refractory disease (no response to VDP) maintained his MRD- CR status until month 7. One additional patient treated presented initially with a high tumor burden and extensive extramedullary (EM) disease. After treatment with GC027 and as confirmed by PET CT scan, all EM lesions resolved. The patient achieved MRD- CR at day 28. All six patients tolerated a single infusion of TruUCAR GC027. No events of neurotoxicity (ICANS) or acute

graft-versus-host disease (aGvHD) were observed. Cytokine release syndrome (CRS) occurred in all patients and was managed with standard of care including Tocilizumab.

GC007g for the treatment of B-cell acute lymphoblastic leukemia (B-ALL):

GC007g is a donor-derived CD19-targeted allogeneic CAR-T cell therapy for the treatment of r/r B-ALL patients who failed transplant and may not be eligible for autologous CAR-T therapy. The allogeneic approach, utilizing T-cells from an HLA-matched healthy donor, has the potential to provide a novel treatment approach to patients not eligible for standard of care.

- Enrolled first patient in the pivotal seamless Phase 1/2 clinical trial to evaluate the safety and efficacy of GC007g in r/r B-ALL patients. (Press Release [March 2021](#)) We received IND approval for the pivotal seamless Phase 1/2 trial of GC007g from China's NMPA in December 2020. (Press Release [Jan 2021](#)) The study is ongoing and accruing patients.

GC019F for the treatment of B-ALL:

GC019F is a FasTCAR-enabled CD19-targeted autologous CAR-T cell therapy for the treatment of r/r B-ALL.

- China's National Medical Products Administration (NMPA) has approved an investigational new drug (IND) application for the Phase I study of GC019F (Press Release [Jan 2021](#))

Corporate Highlights:

- Completed a successful initial public offering of American Depositary Shares (ADSs), raising net proceeds of approximately US\$220 million, and commenced trading on the NASDAQ Global Select Market under the ticker symbol "GRCL" (Press Release [Jan 2021](#))
- Gracell's manufacturing site in Suzhou has been granted the Medical Products Manufacturing Certificate from the Jiangsu Medical Products Administration (Jiangsu is a province/state in China) for the production of CAR-T cell therapy products (Press Release [Jan 2021](#))
- Entered into a Manufacturing Service Agreement with Lonza (SIX:LONN) for clinical manufacturing of Gracell's FasTCAR-enabled CAR-T cell product candidates in the U.S. (Press Release [March 2021](#))
- Expanded executive leadership team with appointment of Jenny (Yajin) Ni, Ph.D., M.D., as Chief Technology Officer. Dr. Ni will strategically lead CAR-T process development, CMC and supply chain management activities at Gracell (Press Release [May 2021](#))

Financial Results for the First Quarter Ended March 31, 2021

Research and development expenses for the three months ended March 31, 2021 were RMB65.4 million (US\$10.0 million), as compared to RMB27.4 million in the corresponding prior year period. This increase was primarily driven by increases of RMB15.7 million (US\$2.4 million) in costs incurred to advance preclinical and clinical pipeline as well as increases of RMB10.5 million (US\$1.6 million) and RMB5.7 million (US\$0.9 million) in depreciation expenses of manufacturing facilities and labor costs due to the further expansion in business, and an increase of RMB6.0 million (US\$0.9 million) in recognition of share-based compensation expenses upon the completion of initial public offering, respectively.

Administrative expenses for the three months ended March 31, 2021 were RMB31.8 million (US\$4.8 million), compared to RMB5.6 million for the corresponding prior year period. This increase was primarily related to an increase of RMB11.5 million (US\$1.8 million) in recognition of share-based compensation expenses upon the completion of initial public offering, an increase of RMB5.8 million (US\$0.9 million) in professional service fee, an increase of RMB3.6 million (US\$0.5 million) attributable to labor costs due to expansion of administrative functions, an increase of RMB1.9 million (US\$0.3 million) of insurance expense for the employees and also an increase of RMB1.0 million (US\$0.1 million) in lease-related expense.

Interest income for the first quarter of 2021 was RMB0.9 million (US\$0.1 million) as compared to RMB1.2 million for the corresponding prior year period. Other income for the first quarter of 2021 was RMB0.1 million (US\$0.02 million) as compared to RMB0.005 million for the corresponding prior year period.

Foreign exchange loss for the three months ended March 31, 2021 was RMB0.3 million (US\$0.05 million), compared to a foreign exchange gain of RMB0.08 million for the corresponding prior year period. This decline in the foreign exchange gain of RMB0.4 million was primarily attributable to unfavorable foreign exchange rate fluctuation during the quarter ended March 31, 2021.

Net loss attributable to ordinary shareholders for the three months ended March 31, 2021 was RMB99.7 million (US\$15.2 million), compared to RMB42.7 million for the corresponding prior year period.

Balance Sheet Highlights

As of March 31, 2021, we had RMB2,169.4 million (US\$331.1 million) in cash and cash equivalents and short-term investments. During the first quarter, we completed an initial public offering of 11,000,000 ADSs, each representing five ordinary shares, at a public offering

price of \$19.00 per ADS. In connection with the initial public offering, we granted the underwriters an option to purchase up to an additional 1,650,000 ADSs at the initial public offering price, which was exercised in full by the underwriters. The net proceeds from these transactions were approximately US\$220 million.

We early adopted ASU 2016-02, Lease (Topic 842), in the first quarter of 2021. As of March 31, 2021, we had operating lease liabilities of RMB25.8 million (US\$3.9 million) and operating lease right-of-use assets of RMB26.1 million (US\$4.0 million).

In the first quarter of 2021, we received a payment from the depository bank of RMB14.5 million (US\$2.2 million) mostly to reimburse the expenses related to the establishment of ADS facility. The payment is initially recognized as a liability and is being amortized over the facility arrangement period. As of March 31, 2021, we had the related other current liabilities of RMB2.9 million (US\$0.44 million) and other non-current liabilities of RMB11.1 million (US\$1.7 million).

In addition, as of March 31, 2021, we had short-term borrowings and current portion of long-term borrowings of RMB60.9 million (US\$9.3 million) and long-term borrowings of RMB51.9 million (US\$7.9 million).

About FasTCAR

CAR-T cells manufactured on Gracell's proprietary FasTCAR platform appear younger, less exhausted and show enhanced proliferation, persistence, bone marrow migration and tumor cell clearance activities as demonstrated in preclinical studies. With next-day manufacturing, FasTCAR is able to significantly improve cell production efficiency which may result in meaningful cost savings, increasing the accessibility of cell therapies for cancer patients.

About TruUCAR

TruUCAR is Gracell's proprietary technology platform and is designed to generate high-quality allogeneic CAR-T cell therapies that can be administered "off-the-shelf" at lower cost and with greater convenience. With differentiated design enabled by gene editing, TruUCAR is designed to control host vs graft rejection (HvG) as well as graft vs host disease (GvHD) without the need of being co-administered with additional immunosuppressive drugs.

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. For more information on Gracell, please visit www.gracellbio.com

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Exchange Rate Information

This announcement contains translations of certain RMB amounts into U.S. dollars at a specified rate solely for the convenience of the reader. Unless otherwise noted, all translations from Renminbi to U.S. dollars are made at a rate of RMB6.5518 to US\$1.00, the rate in effect as of March 31, 2021 published by the Federal Reserve Board.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the expected trading commencement and closing date of the offering. The words "anticipate," "look forward to," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including factors discussed in the section entitled "Risk Factors" in Gracell's most recent annual report on Form 20-F as well as discussions of potential risks, uncertainties, and other important factors in Gracell's subsequent filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Gracell specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. Readers should not rely upon the information on this page as current or accurate after its publication date.

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Unaudited Consolidated Balance Sheets

(All amounts in thousands, except for share and per share data)

	As of		US\$
	December 31,	As of March 31,	
	2020	2021	
	RMB	RMB	
ASSETS			
Current assets:			
Cash and cash equivalents	754,308	2,157,833	329,350
Short-term investments	18,743	11,614	1,773
Prepayments and other current assets	42,418	54,899	8,379
Total current assets	815,469	2,224,346	339,502
Property, equipment and software	119,083	117,732	17,969
Operating lease right-of-use assets	—	26,077	3,980
Other non-current assets	30,398	19,902	3,037
TOTAL ASSETS	964,950	2,388,057	364,488
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT			
Current liabilities:			
Short-term borrowings	49,990	59,990	9,156
Operating lease liabilities, current	—	16,244	2,479
Current portion of long-term borrowings	970	874	133
Accruals and other current liabilities	42,401	43,912	6,702
Total current liabilities	93,361	121,020	18,470
Long-term borrowings	51,926	51,926	7,925
Operating lease liabilities, non-current	—	9,597	1,465
Other non-current liabilities	—	11,078	1,691
TOTAL LIABILITIES	145,287	193,621	29,551
Commitments and contingencies			
Mezzanine equity:			
Series A convertible redeemable preferred shares	110,468	—	—
Series B-1 convertible redeemable preferred shares	142,481	—	—
Series B-2 convertible redeemable preferred shares	495,799	—	—
Series C convertible redeemable preferred shares	658,788	—	—
Total mezzanine equity	1,407,536	—	—
Shareholders' equity (deficit):			
Ordinary shares	68	222	34
Additional paid-in capital	—	2,858,181	436,244
Accumulated other comprehensive loss	(23,912)	(284)	(43)
Accumulated deficit	(564,029)	(663,683)	(101,298)
Total shareholders' equity (deficit)	(587,873)	2,194,436	334,937
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY (DEFICIT)	964,950	2,388,057	364,488

Unaudited Consolidated Statements of Comprehensive Loss
(All amounts in thousands, except for share and per share data)

	For the three months ended March 31,		
	2020	2021	
	RMB	RMB	US\$
Expenses			
Research and development expenses	(27,355)	(65,433)	(9,987)
Administrative expenses	(5,625)	(31,759)	(4,847)
	(32,980)	(97,192)	(14,834)
Loss from operations			
Interest income	1,163	932	142
Interest expense	(206)	(1,235)	(188)
Other income	5	128	20
Foreign exchange gain (loss), net	79	(298)	(45)
Others, net	(15)	—	—
	(31,954)	(97,665)	(14,905)
Loss before income tax			
Income tax expense	—	—	—
	(31,954)	(97,665)	(14,905)
Net loss			
Accretion of convertible redeemable preferred shares to redemption value	(10,739)	(1,989)	(304)
	(42,693)	(99,654)	(15,209)
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(42,693)	(99,654)	(15,209)
Other comprehensive income			
Foreign currency translation adjustments, net of nil tax	3,524	23,629	3,607
	(39,169)	(76,025)	(11,602)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(39,169)	(76,025)	(11,602)
Weighted average number of ordinary shares used in per share calculation:			
—Basic	99,044,776	304,488,419	304,488,419
—Diluted	99,044,776	304,488,419	304,488,419
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders			
—Basic	(0.43)	(0.33)	(0.05)
—Diluted	(0.43)	(0.33)	(0.05)