



Gracell Biotechnologies Reports Fourth Quarter and Full Year 2021 Unaudited Financial Results and Provides Corporate Update

- Plan to file U.S. IND for lead program FasTCAR-T GC012F for relapse and/or refractory multiple myeloma (RRMM) during second half of 2022
- Allogeneic TruUCAR-T GC502 currently being investigated in a first-in-human investigator-initiated trial (IIT) in China in B-cell malignancies with early data to be presented at AACR 2022
- Well-funded with cash runway into 2024
- Management to host conference call at 8:00 a.m. ET today

PALO ALTO, Calif. and SUZHOU, China, March 14, 2022 (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 fourth quarter and full year unaudited financial results for the period ended December 31, 2021, and provided corporate updates.

"2021 was a year of exceptional growth as we progressed the development of our differentiated cell therapy platforms and continued to broaden our research and clinical capabilities," said Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. "For our lead candidate GC012F developed on the next-day manufacturing autologous FasTCAR CAR-T platform, we continued enrolling patients in our RRMM clinical IIT and have expanded into a new indication, B-NHL. For our allogeneic TruUCAR CAR-T platform, we will be presenting at AACR 2022 the first-in-human data of our lead product candidate GC502, the CD19/CD7 dual-directed allogeneic CAR-T for B-cell malignancies, which will showcase the TruUCAR platform's broad applicability. Concurrently, we are advancing our SMART CART™ platform for the treatment of solid tumors and plan to enter our first-in-human study of mesothelin-targeted GC503 in 2022. Simultaneously, we are expanding our U.S. capabilities and recently opened our Innovation Center in San Diego, California. 2022 is poised to be a fast-paced, transformative year for Gracell as we advance towards our goal of providing safer, more efficacious and accessible treatment options to patients in need globally."

Pipeline Highlights

FasTCAR Platform: Next-day manufacturing for autologous CAR-T cell therapy

GC012F: autologous CAR-T therapeutic candidate dual-targeting B cell maturation antigen (BCMA) and CD19, currently being evaluated for the treatment of multiple myeloma and B-cell non-Hodgkin's lymphoma (B-NHL).

- Dosed first patients in the Phase 1 IIT in China, evaluating GC012F for the treatment of relapsed or refractory (r/r) B-NHL.
- Plan to submit the U.S. IND filing for RRMM in the second half of 2022 and the revised timeline is due to manufacturing capacity constraints at the CDMO.
- Expect to submit the China IND filing for RRMM in 2022.
- Recently requested and being granted Orphan Drug Designation for GC012F for the treatment of multiple myeloma.

TruUCAR Platform: Novel designs enabling "off-the-shelf" allogeneic CAR-T therapy

GC502: TruUCAR-enabled CD19/CD7 dual-directed allogeneic CAR-T cell therapy being studied in an ongoing Phase 1 IIT in China for the treatment of B-cell malignancies. GC502 is manufactured from T cells of non-HLA (human leukocyte antigen)-matched healthy donors.

- First-in-human data from China IIT study in B-cell acute lymphoblastic leukemia (B-ALL) patients will be presented at AACR on April 12, 2022.

GC027: TruUCAR-enabled CD7-targeted allogeneic CAR-T cell therapy for the treatment of T cell acute lymphoblastic leukemia (T-ALL).

- Target to have regulatory interactions globally and in China in the next 12 months.

SMART CART™ Platform: With unique construct to take advantage of the suppressive tumor microenvironment (TME) and effectively combat solid tumors, SMART CART™ is designed to enhance CAR-T cell proliferation and duration of killing, and to resist exhaustion with improved persistence of CAR-T cells.

- On track to commence patient enrollment in a China IIT for GC503 in mesothelin-positive solid tumors including ovarian cancer in

2022.

- Plan to commence a China IIT for GC506 in CLDN18.2-positive solid tumors.

GC007g for the treatment of B-ALL: GC007g is an allogeneic CD19-targeted CAR-T cell therapy, derived from HLA-matched donor, for the treatment of r/r B-ALL patients who failed transplant and may not be eligible for autologous CAR-T therapy.

- Registrational Phase 1/2 clinical trial under a China IND is ongoing for the treatment of r/r B-ALL. Study is now enrolling patients in the second dosing cohort prior to entering the Phase 2 part of the seamless-design study.

Corporate Highlights

- Unveils U.S. Innovation Center: The Company's new research facility, the Innovation Center, has opened in San Diego, California, during the first quarter of 2022.

Conference Call and Webcast Details:

Monday, March 14, 2022 @ 8:00am ET

Investor domestic dial-in: 833-693-0545

Investor international dial-in: +1 661-407-1586

Conference ID: 9957906

Live webcast link: <https://ir.gracellbio.com/news-events/events-and-presentations>

A replay of the webcast will be available on ir.gracellbio.com shortly after the conclusion of the event for 90 days.

Financial Results for the Fourth Quarter and Full Year 2021

As of December 31, 2021, the Company had RMB1,832.6 million (US\$287.6 million) in cash and cash equivalents and short-term investments. The Company completed an initial public offering in January 2021 with net proceeds of approximately US\$220 million.

Net loss attributable to ordinary shareholders for the three months ended December 31, 2021 was RMB128.6 million (US\$20.2 million), compared to RMB99.9 million for the same period in 2020. Net loss attributable to ordinary shareholders for the full year ended December 31, 2021 was RMB453.7 million (US\$71.2 million), compared to RMB274.6 million for the same period in 2020.

Research and Development Expenses

Research and development expenses for the three months ended December 31, 2021 were RMB107.6 million (US\$16.9 million), as compared to RMB60.7 million for the same period in 2020. For the full year ended December 31, 2021, research and development expenses were RMB326.9 million (US\$51.3 million) compared to RMB168.8 million for the same period in 2020. The increase was primarily due to the increased spending on research, development, and clinical trials, as well as higher payroll and personnel expenses attributable to increased headcount, higher facility-related costs in support of continuing expansion of research and development activities and increased expenses in share-based compensation.

Administrative Expenses

Administrative expenses for the three months ended December 31, 2021 were RMB32.0 million (US\$5.0 million), compared to RMB24.8 million for the same period in 2020. For the full year ended December 31, 2021, administrative expenses were RMB137.0 million (US\$21.5 million) as compared to RMB45.6 million for the same period in 2020. The increase was primarily driven by an increase in recognition of share-based compensation expenses as well as an increase in payroll and personnel expenses due to the expansion of administrative functions.

The Company early adopted ASU 2016-02, Lease (Topic 842), in the first quarter of 2021. As of December 31, 2021, the Company had operating lease liabilities of RMB32.4 million (US\$5.1 million) and operating lease right-of-use assets of RMB29.7 million (US\$4.7 million).

As of December 31, 2021, 337,969,926 ordinary shares, par value of US\$0.0001 per share, were issued and outstanding. As of December 31, 2021, 14,550,935 options were granted and 13,102,590 options were outstanding, and 1,494,650 restricted share units ("RSUs") were granted under our employee stock option plan. Each of our ADS represents five ordinary shares.

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 of unique

genes, 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 SMART CART™

SMART CART™ is Gracell's proprietary technology platform designed to strengthen the functionality of CAR-T cells further, and aims to overcome tumor microenvironment (TME). SMART CART™ includes altered expression of the receptor and signaling mechanism of an inhibitory TME molecule to enhance expansion and persistence and to reduce the exhaustion of CAR T cells. This design reverses and turns immunosuppressive signals of TME into stimulatory reactions of CAR-T cells. SMART CART™ technology can be applied to many targets for the treatment of solid tumors.

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, TruUCAR and SMART CART™ 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 cell quality, high therapy cost and lack of effective CAR-T therapies for solid tumors. For more information on Gracell, please visit www.gracellbio.com. Follow @GracellBio on [LinkedIn](https://www.linkedin.com/company/gracell-bio)

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 RMB 6.3726 to US\$1.00, the rate in effect as of December 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 offering's expected trading commencement and closing date. 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. Gracell specifically disclaims any obligation to update any forward-looking statement, whether due to 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 Condensed Consolidated Balance Sheets

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

	As of December 31, <u>2020</u>	As of December 31, <u>2021</u>	
	RMB	RMB	US\$
ASSETS			
Current assets:			
Cash and cash equivalents	754,308	1,829,006	287,011
Short-term investments	18,743	3,615	567
Prepayments and other current assets	42,418	52,459	8,232
Total current assets	815,469	1,885,080	295,810
Property, equipment and software	119,083	123,818	19,430

Operating lease right-of-use assets	—	29,652	4,653
Other non-current assets	30,398	21,587	3,387
TOTAL ASSETS	964,950	2,060,137	323,280
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY(DEFICIT)			
Current liabilities:			
Short-term borrowings	49,990	66,100	10,373
Operating lease liabilities, current	—	17,527	2,750
Current portion of long-term borrowings	970	2,376	373
Accruals and other current liabilities	42,401	69,120	10,846
Total current liabilities	93,361	155,123	24,342
Long-term borrowings	51,926	54,349	8,529
Operating lease liabilities, non-current	—	14,830	2,327
Other non-current liabilities	—	8,464	1,328
TOTAL LIABILITIES	145,287	232,766	36,526
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	223	35
Additional paid-in capital	—	2,902,856	455,521
Accumulated other comprehensive loss	(23,912)	(57,936)	(9,091)
Accumulated deficit	(564,029)	(1,017,772)	(159,711)
Total shareholders' equity (deficit)	(587,873)	1,827,371	286,754
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY(DEFICIT)	964,950	2,060,137	323,280

Unaudited Condensed Consolidated Statements of Comprehensive Loss

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

	For the three months ended December			For the year ended December 31,		
	31,		US\$	2020		US\$
	2020	2021		RMB	RMB	
	RMB	RMB	US\$	RMB	RMB	US\$
Revenue						
Licensing and collaboration revenue	—	—	—	—	366	57
Expenses						
Research and development expenses	(60,693)	(107,582)	(16,882)	(168,830)	(326,899)	(51,298)
Administrative expenses	(24,785)	(31,998)	(5,021)	(45,566)	(137,040)	(21,505)
Loss from operations	(85,478)	(139,580)	(21,903)	(214,396)	(463,573)	(72,746)
Interest income	454	3,466	544	2,870	9,116	1,430
Interest expense	(805)	(1,327)	(208)	(2,155)	(5,063)	(794)
Other income	2,913	8,254	1,295	4,707	9,120	1,431
Foreign exchange income (loss), net	(677)	606	95	(2,914)	(1,297)	(204)
Others, net	—	(4)	(1)	(12)	(57)	(9)
Loss before income tax	(83,593)	(128,585)	(20,178)	(211,900)	(451,754)	(70,892)
Income tax expense	—	—	—	—	—	—

Net loss	(83,593)	(128,585)	(20,178)	(211,900)	(451,754)	(70,892)
Accretion of convertible redeemable preferred shares to redemption value	(16,341)	—	—	(62,733)	(1,989)	(312)
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(99,934)	(128,585)	(20,178)	(274,633)	(453,743)	(71,204)
Other comprehensive loss						
Foreign currency translation adjustments, net of nil tax	(18,796)	(30,225)	(4,743)	(20,753)	(34,023)	(5,339)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(118,730)	(158,810)	(24,921)	(295,386)	(487,766)	(76,543)
Weighted average number of ordinary shares used in per share calculation:						
—Basic	99,044,776	337,853,025	337,853,025	99,044,776	328,866,599	328,866,599
—Diluted	99,044,776	337,853,025	337,853,025	99,044,776	328,866,599	328,866,599
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders						
—Basic	(1.01)	(0.38)	(0.06)	(2.77)	(1.38)	(0.22)
—Diluted	(1.01)	(0.38)	(0.06)	(2.77)	(1.38)	(0.22)