



Gracell Biotechnologies Reports Second Quarter 2022 Unaudited Financial Results and Provides Corporate Update

- Presented updated clinical data from an investigator-initiated trial (IIT) evaluating FasTCAR GC012F for the treatment of relapsed/refractory multiple myeloma (r/r MM) at ASCO and EHA 2022, which underscored the deep response with a 100% MRD negativity rate
- Presented first-in-human data of GC012F in relapsed/refractory B-cell Non-Hodgkin's lymphomas (r/r B-NHL) at EHA 2022
- Presented updated results from an IIT evaluating allogeneic TruUCAR GC502 in relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL) at EHA 2022
- Continued enrollment in an IIT evaluating GC012F in newly diagnosed multiple myeloma (NDMM) patients
- Completed the Phase 1 portion of the registrational Phase 1/2 clinical trial under a China IND for GC007g in r/r B-ALL
- Strengthened leadership team with appointments of Dr. Wendy Li as Chief Medical Officer and Dr. Samuel Zhang as Chief Business Officer
- Well-funded with cash runway into 2024
- Management to host conference call at 8:00 a.m. ET today

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China, Aug. 15, 2022 (GLOBE NEWSWIRE) -- Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell" or "Company"), a global clinical-stage biopharmaceutical company dedicated to discovering and developing highly efficacious and affordable cell therapies for the treatment of cancer, today reported second quarter unaudited financial results for the period ended June 30, 2022, and provided corporate updates.

"In recent months, we have made significant clinical progress for our lead candidate, the BCMA/CD19 dual-targeting FasTCAR GC012F. The updated clinical data from the fully enrolled r/r MM study showcased the deep response achieved, favorable safety profile and the differentiated next-day manufacturing at both ASCO and EHA. We are encouraged by the consistently positive data and are on track to complete the IND submissions for GC012F in r/r MM in both the U.S. and China before year end," said Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. "We have also reported at EHA the first-in-human data for GC012F in r/r B-NHL and the updated data for the allogeneic GC502 in r/r B-ALL. Our frontline NDMM study of GC012F is actively enrolling patients. I am very pleased with the depth of our differentiated CAR-T pipeline and looking forward to reporting clinical data from a few ongoing clinical studies at major medical meeting later this year. We strengthened our leadership team in recent weeks and the entire Gracell team is committed to achieving our vision of making CAR-T therapy more effective, safer and more broadly accessible to patients."

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 r/r MM, NDMM and r/r B-NHL.

- Dataset from an IIT evaluating GC012F for the treatment of r/r MM presented as oral presentations at American Society of Clinical Oncology Annual Meeting (ASCO 2022) and European Hematology Association 2022 Congress (EHA 2022)
 - Underscored the deep responses achieved, including a 100% MRD negativity rate in all patients treated, as of the June 8, 2022 cutoff date following enrollment completion with 29 patients, of which 90% were classified as high risk
 - Demonstrated consistently favorable safety profile and promising mDOR of 15.7 months in mostly high risk and heavily pretreated patients
- Enrollment progressing in an IIT in China evaluating GC012F in NDMM
- Presented initial data from an ongoing IIT evaluating GC012F for the treatment of r/r B-NHL at EHA 2022
 - Demonstrated potent and fast activity with 100% CR rate at one-month observed in all three patients with r/r B-NHL (3/3 DLBCL) including patients with bulky disease, as of the February 22, 2022 cutoff date
- On track to submit the U.S. and China IND filings for r/r MM in the second half of 2022

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 (non-human leukocyte antigen) matched healthy donors.

- Updated data from single-arm, open-label IIT with longer follow-up of GC502 in r/r B-ALL presented at EHA 2022.
 - As of the February 22, 2022 cutoff date, data from four patients across two formulations demonstrated very promising response rates at their one-month assessments, manageable and reversible adverse events, and robust expansion of GC502

GC027: TruUCAR-enabled CD7-targeted allogeneic CAR-T cell therapy for the treatment of relapsed/refractory T cell acute lymphoblastic leukemia (r/r 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 in 2022.
- Plan to commence a China IIT for GC506 in CLDN18.2-positive solid tumors.

Donor-derived CAR GC007g: 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.

- Completed the Phase 1 portion of the registrational Phase 1/2 clinical trial underway under a China IND for the treatment of r/r B-ALL. On track to commence Phase 2 portion in the third quarter 2022.

Executive Appointments

- Dr. Wendy (Wenling) Li as Chief Medical Officer: Dr. Li will oversee Gracell's clinical development activities, including the advancement of Gracell's pipeline of autologous and allogeneic product candidates across the Company's multiple proprietary technology platforms. She brings to Gracell over 20 years of experience leading all critical aspects of clinical development and medical affairs at early-stage and large pharmaceutical organizations in the U.S. and China.
- Dr. Samuel Zhang as Chief Business Officer: Dr. Zhang will be responsible for strategic leadership of Gracell's global business development and corporate strategy. He brings to Gracell over 20 years of industry experience across drug development stages, and has a long history of managing strategic alliances and collaborations at both large pharmaceutical and small biotech companies.

Financial Results for the Second Quarter Ended June 30, 2022

As of June 30, 2022, the Company had RMB1,707.3 million (US\$254.9 million) in cash and cash equivalents and short-term investments. In addition, the Company had short-term borrowings and current portion of long-term borrowings of RMB102.3 million (US\$15.3 million) and long-term borrowings of RMB53.0 million (US\$7.9 million).

Net loss attributable to ordinary shareholders for the three months ended June 30, 2022 was RMB146.3 million (US\$21.8 million), compared to RMB96.2 million for the corresponding prior year period.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2022 were RMB117.1 million (US\$17.5 million), compared to RMB65.3 million in the corresponding prior year period. 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, and higher facility-related costs.

Administrative Expenses

Administrative expenses for the three months ended June 30, 2022 were RMB28.8 million (US\$4.3 million), compared to RMB30.4 million for the corresponding prior year period. The decrease was primarily driven by a decrease in professional service and a decrease in share-based compensation expenses.

Interest income for the three months ended June 30, 2022 was RMB2.7 million (US\$0.4 million), compared to RMB1.7 million for the corresponding prior year period. Other income for the three months ended June 30, 2022 was RMB1.8 million (US\$0.3 million), compared to RMB5 thousand for the corresponding prior year period.

As of June 30, 2022, 338,370,624 ordinary shares, par value of US\$0.0001 per share, were issued and outstanding. As of June 30, 2022, 16,750,761 options were granted and 14,837,748 options were outstanding, and 1,974,391 restricted share units ("RSUs") were granted under our employee stock option plan. Each of our ADS represents five ordinary shares.

Conference Call and Webcast Details:

Monday, August 15, 2022 @ 8:00 a.m. ET
 Investor domestic dial-in: (800) 715-9871
 Investor international dial-in: (646) 307-1963

Conference ID: 7693510

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.

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 module 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 and TruUCAR technology platforms and SMART CART™ technology module, 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 and 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 6.6981 to US\$1.00, the rate in effect as of June 30, 2022 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. 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.

Unaudited Condensed Consolidated Balance Sheets

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

	As of	As of June 30,	
	December 31,	2022	
	2021	RMB	US\$
	RMB	RMB	US\$
ASSETS			
Current assets:			
Cash and cash equivalents	1,829,006	1,535,118	229,187
Short-term investments	3,615	172,199	25,709

Prepayments and other current assets	52,459	31,993	4,776
Total current assets	1,885,080	1,739,310	259,672
Property, equipment and software, net	123,818	108,247	16,161
Operating lease right-of-use assets	29,652	22,174	3,310
Other non-current assets	21,587	29,450	4,397
TOTAL ASSETS	2,060,137	1,899,181	283,540
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Accruals and other current liabilities	69,120	92,978	13,881
Short-term borrowings	66,100	99,600	14,870
Operating lease liabilities, current	17,527	19,280	2,878
Amounts due to related parties	—	2,563	383
Current portion of long-term borrowings	2,376	2,684	401
Total current liabilities	155,123	217,105	32,413
Operating lease liabilities, non-current	14,830	7,547	1,127
Long-term borrowings	54,349	52,962	7,907
Other non-current liabilities	8,464	7,764	1,159
TOTAL LIABILITIES	232,766	285,378	42,606
Shareholders' equity:			
Ordinary shares	223	223	33
Additional paid-in capital	2,902,856	2,918,585	435,733
Accumulated other comprehensive (loss)/gain	(57,936)	17,655	2,636
Accumulated deficit	(1,017,772)	(1,322,660)	(197,468)
Total shareholders' equity	1,827,371	1,613,803	240,934
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	2,060,137	1,899,181	283,540

Unaudited Condensed Consolidated Statements of Comprehensive Loss

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

	For the three months ended June 30,			For the six months ended June 30,		
	2021	2022		2021	2022	
	RMB	RMB	US\$	RMB	RMB	US\$
Expenses						
Research and development expenses	(65,267)	(117,058)	(17,476)	(130,700)	(238,895)	(35,666)
Administrative expenses	(30,423)	(28,766)	(4,295)	(62,182)	(66,656)	(9,951)
Loss from operations	(95,690)	(145,824)	(21,771)	(192,882)	(305,551)	(45,617)
Interest income	1,734	2,702	403	2,666	5,198	776
Interest expense	(1,412)	(1,657)	(247)	(2,647)	(3,082)	(460)
Other income	5	1,797	268	133	1,940	290
Foreign exchange gain, net	(803)	(3,324)	(496)	(1,101)	(3,395)	(507)
Others, net	(53)	1	—	(53)	2	—
Loss before income tax	(96,219)	(146,305)	(21,843)	(193,884)	(304,888)	(45,518)
Income tax expense	—	—	—	—	—	—
Net loss	(96,219)	(146,305)	(21,843)	(193,884)	(304,888)	(45,518)
Accretion of convertible redeemable preferred shares to redemption value	—	—	—	(1,989)	—	—
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(96,219)	(146,305)	(21,843)	(195,873)	(304,888)	(45,518)
Other comprehensive loss						
Foreign currency translation adjustments, net of nil tax	(34,767)	82,028	12,246	(11,138)	75,591	11,285

Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	<u>(130,986)</u>	<u>(64,277)</u>	<u>(9,597)</u>	<u>(207,011)</u>	<u>(229,297)</u>	<u>(34,233)</u>
Weighted average number of ordinary shares used in per share calculation:						
—Basic	336,167,006	338,355,742	338,355,742	320,415,223	338,244,214	338,244,214
—Diluted	336,167,006	338,355,742	338,355,742	320,415,223	338,244,214	338,244,214
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders						
—Basic	(0.29)	(0.43)	(0.06)	(0.61)	(0.90)	(0.13)
—Diluted	(0.29)	(0.43)	(0.06)	(0.61)	(0.90)	(0.13)

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