PRESS RELEASE

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

SUZHOU, China and PALO ALTO, Calif., Aug. 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 second quarter of the year and recent business highlights. Gracell will host a conference call today, Tuesday, August 17, at 8:00 am Eastern Time.

"We are very pleased with the significant progress we have made in 2021 across our key clinical, manufacturing and corporate objectives," commented Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. "Our innovative portfolio of autologous and allogeneic CAR-T cell therapies, built upon our rich cell therapy and gene editing expertise and proprietary FasTCAR and TruUCAR technology platforms, continues to meet key milestones and demonstrate encouraging and competitive therapeutic potential across multiple difficult to treat hematologic malignancies and solid tumors."

"Longer-term follow-up data for GC012F, our BCMA/CD19 dual-targeting CAR-T therapy for multiple myeloma designed on the next-day manufacturing FasTCAR platform, was presented at the ASCO 2021 Annual Meeting and the EHA 2021 Congress in June. We continue to see fast, deep and durable responses in a difficult to treat, predominantly high-risk patient population. Updates on longer-term follow-up for our study in T-ALL for GC027, our lead TruUCAR candidate, an off-the-shelf, stand-alone allogeneic CAR-T cell therapy, was presented at the AACR 2021 Annual Meeting this April. Data continues to be encouraging and we are planning on enrolling additional patients to expand the indication to AML. In March, we announced enrollment of the first patient in our pivotal Phase 1/2 clinical study of GC007g in China, an allogeneic donor-derived anti-CD19 CAR-T cell therapy for the treatment of r/r B-ALL and we are pleased to announce completion of the first dosing cohort for GC007g."

Dr. Cao continued, "We are very happy to announce the timely expansion of our US team. In spring, we appointed Dr. Jenny (Yajin) Ni as Chief Technology Officer. Seasoned in CAR-T cell therapy CMC development and having successfully lead process development at both Pfizer and Allogene Therapeutics, Dr. Ni's focus is supporting a smooth technology transfer to Lonza for our FasTCAR-enabled product candidate GC012F. In addition, we are excited about Dr. Grace Jiang joining Gracell as our Head of U.S. Regulatory Affairs reporting to our Chief Medical Officer Dr. Sersch. Dr. Jiang brings nearly 20 years of experience in biotechnology companies, including at Amgen, in regulatory affairs with filing experience in Multiple Myeloma. Dr. Ni and Dr. Jiang will be instrumental as we continue to advance our product development, and these key appointments also mark an important step to advance our presence in the U.S."

"As we enter the second half of 2021, we will continue to build on our solid progress achieved so far. In the coming months of this year, we are planning on advancing exciting early pipeline candidates into clinical studies in China. We will enhance our R&D capabilities in the U.S., with our ongoing manufacturing collaboration with Lonza supporting a U.S. IND submission for the FasTCAR candidate GC012F in the first half of 2022. We also plan to expand our manufacturing capacity by developing a second facility in Suzhou, China in addition to our state-of-the-art, 66,000 sq. ft. GMP manufacturing facility, designed for fully-closed production capabilities to reduce contamination risks and optimize cost-efficiency. These clinical and operational developments will bring Gracell closer to delivering accessible and highly efficacious treatments for patients across a wider range of malignancies," Dr. Cao concluded.

Second Quarter 2021 and Subsequent Highlights

GC012F for the treatment of multiple myeloma (MM):
GC012F is a FasTCAR-enabled dual-targeting BCMA/CD19 autologous chimeric antigen receptor (CAR)-T cell therapy that is currently being studied in an ongoing Phase 1 investigator-initiated trial (IIT) in China for the treatment of MM patients who are relapsed from or refractory to (r/r) prior therapies.

- **Interim data presented at ASCO & EHA.** Interim data presented at the ASCO 2021 Annual Meeting and the EHA 2021 Congress (Press Release May 2021). As of January 12, 2021, the study had enrolled and treated 19 patients at three dose levels with the highest dose level of $3x10^5$ cells/kg. Since the last update (reported at ASH 2020), additional patients were treated at the highest dose level.
- **High risk patient population.** Notably, 18 of the 19 patients (94.7%) treated were classified as high-risk according to mSMART 3.0 guidelines and patients had received a median of 5 prior lines of therapy. 94.7% (18/19) of the patients were triple exposed to a PI, IMiD, and at least a third treatment modality, including anti-CD38 targeted therapy.
- **100% MRD- sCR at dose level 3.** Early Overall Response Rate (ORR) shows a promising 94.7% (18/19) with all responses being VGPR or better (sCR), highlighting fast, deep and durable responses in all dose levels. 100% of the patients treated at the

highest dose level (n=9) obtained MRD- sCR.

- **Favorable safety profile.** The safety profile of GC012F was consistent with previous findings with mostly low grade of cytokine release syndrome (CRS) (84% Grade 1/2, 11% (n=2) patients Grade 3). No Grade 4 or 5 CRS and no ICANS (immune effector cell-associated neurotoxicity) were observed in any of the 19 patients. Treatment-emergent adverse events (TEAEs) presented predominantly as cytopenias and AST increase. All TEAEs resolved with standard therapy. Patients are continued to be followed for efficacy and safety.
- **IND in 1H2022.** IND application submission in both the US and China planned within the first half of 2022.

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 a human leukocyte antigen (HLA)-matched healthy donor, has the potential to provide a novel treatment approach to patients not eligible for standard of care.

- **First patient enrolled.** 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).
- **First dosing cohort completed.** Successful enrollment of first dosing cohort in the phase 1/2 seamless design study was completed.

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-matched healthy donors.*

- **Longer-term follow-up data presented AACR.** 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 $1.5x10^7$ cells/kg.
- **Longest ongoing DOR 16.8 months.** 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 regimen) 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.
- **No ICANS or aGvHD.** All six patients tolerated a single infusion of TruUCAR GC027. No neurotoxicity events (ICANS) or acute graft-versus-host disease (aGvHD) were observed. CRS occurred in all patients and was managed with standard of care including tocilizumab. Overall safety findings were consistent with previous observations.
- **IND in 2022.** IND application submission in both the US and China planned in 2022.

Corporate Highlights:

- **Expanded executive leadership.** Expanded executive leadership team with the appointment of Dr. Jenny (Yajin) Ni, 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)
- **Exclusive License Agreement with FutureGen Biopharmaceutical Co., Ltd.** On May 11, 2021, we entered into an exclusive license agreement with FutureGen Biopharmaceutical Co., Ltd. (“FutureGen”) under which FutureGen grants to Gracell an exclusive, worldwide, sublicensable license under FutureGen’s patent rights to research, develop, manufacture, commercialize, and otherwise exploit the patent rights in the field of engineered or modified immune cell therapies for solid tumors. (Press Release August 2021)

Financial Results for the Second Quarter Ended June 30, 2021

Research and development expenses for the three months ended June 30, 2021 were RMB65.3 million (US$10.1 million), as compared to RMB40.8 million in the corresponding prior year period. This increase was primarily driven by increases of RMB8.2 million (US$1.3 million) in labor costs due to the further expansion in business as well as an increases of RMB6.9 million (US$1.1 million) and RMB5.1 million (US$0.8 million) in depreciation expenses of research and development facilities and in costs incurred to advance preclinical and clinical pipeline, an increase of RMB2.8 million (US$0.4 million) in professional service expenses and an increase of RMB1.8 million (US$0.3 million) in recognition of share-based compensation expenses upon the completion of initial public offering, respectively.

Administrative expenses for the three months ended June 30, 2021 were RMB30.4 million (US$4.7 million), compared to RMB7.0 million for the corresponding prior year period. This increase was primarily related to an increase of RMB7.7 million (US$1.2 million) in recognition of share-based compensation expenses upon the completion of initial public offering, an increase of RMB6.3 million (US$1.0 million) attributable to labor costs due to expansion of administrative functions, an increase of RMB5.2 million (US$0.8 million) in financial and legal consulting fee, an increase of RMB2.3 million (US$0.4 million) of insurance expense for the employees and also an increase of RMB0.7 million (US$0.1 million) in lease-related expense.

Interest income for the second quarter of 2021 was RMB1.7 million (US$0.3 million) as compared to RMB1.0 million for the corresponding prior year period.

Foreign exchange loss for the three months ended June 30, 2021 was RMB0.8 million (US$0.1 million), compared to a foreign exchange loss of RMB0.1 million for the corresponding prior year period. This increase in the foreign exchange loss of RMB0.7 million was primarily attributable to unfavorable foreign exchange rate fluctuating during the quarter ended June 31, 2021.

Net loss attributable to ordinary shareholders for the three months ended June 30, 2021 was RMB96.2 million (US$14.9 million), compared to RMB63.1 million for the corresponding prior year period.

Balance Sheet Highlights

As of June 30, 2021, we had RMB2,053.6 million (US$318.1 million) in cash and cash equivalents and short-term investments. During the first half of the year, we completed an initial public offering of 11,000,000 American Depositary Shares ("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 June 30, 2021, we had operating lease liabilities of RMB39.5 million (US$6.1 million) and operating lease right-of-use assets of RMB39.2 million (US$6.1 million).

In the first quarter of 2021, we received a payment from the depositary 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 June 30, 2021, we had the related other current liabilities of RMB2.9 million (US$0.44 million) and other non-current liabilities of RMB10.1 million (US$1.6 million).

In addition, as of June 30, 2021, we had short-term borrowings and current portion of long-term borrowings of RMB58.1 million (US$9.0 million) and long-term borrowings of RMB55.6 million (US$8.6 million).

As of June 30, 2021, 336,217,511 ordinary shares, par value of US$0.0001 per share, were issued and outstanding. As of June 30, 2021, 11,707,435 options were granted and 10,946,710 options were outstanding, and 303,030 restricted share units (“RSUs”) were granted under our employee stock option plan. Each of our ADS represents five ordinary shares.

Conference Call Details

Tuesday, August 17, 2021 at 8:00 am ET
Investor domestic dial-in: 877-407-0784
Investor international dial-in: +1 201-689-8560
Conference ID: 13722146
Webcast link: https://ir.gracellbio.com/news-events/events-and-presentations

The webcast replay will be available on the Gracell website at ir.gracellbio.com for 90 days following the completion of the call.

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 RMB6.4566 to US$1.00, the rate in effect as of June 30, 2021 published by the Federal Reserve Board.

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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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 Condensed Consolidated Balance Sheets

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

	As of December 31,	As of June 30,	
	2020	2021	
	RMB	RMB	US$
ASSETS			
Current assets:			
Cash and cash equivalents	754,308	2,049,897	317,489
Short-term investments	18,743	3,733	578
Prepayments and other current assets	42,418	62,938	9,747
Total current assets	**815,469**	**2,116,568**	**327,814**
Property, equipment and software	119,083	122,439	18,963
Operating lease right-of-use assets	—	39,239	6,077
Other non-current assets	30,398	13,532	2,096
TOTAL ASSETS	**964,950**	**2,291,778**	**354,950**
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT			
Current liabilities:			
Short-term borrowings	49,990	56,090	8,687
Operating lease liabilities, current	—	18,184	2,816
Current portion of long-term borrowings	970	1,978	306
Accruals and other current liabilities	42,401	55,616	8,614
Total current liabilities	**93,361**	**131,868**	**20,423**
Long-term borrowings	51,926	55,646	8,619
Operating lease liabilities, non-current	—	21,288	3,297

Other non-current liabilities	—	10,104	1,565
TOTAL LIABILITIES	**145,287**	**218,906**	**33,904**
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' deficit:			
Ordinary shares	68	222	34
Additional paid-in capital	—	2,867,603	444,135
Accumulated other comprehensive loss	(23,912)	(35,051)	(5,429)
Accumulated deficit	(564,029)	(759,902)	(117,694)
Total shareholders' deficit	**(587,873)**	**2,072,872**	**321,046**
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT	**964,950**	**2,291,778**	**354,950**

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,		
	2020	2021		2020	2021	
	RMB	RMB	US$	RMB	RMB	US$
Expenses						
Research and development expenses	(40,796)	(65,267)	(10,108)	(68,151)	(130,700)	(20,243)
Administrative expenses	(6,972)	(30,423)	(4,712)	(12,597)	(62,182)	(9,631)
Loss from operations	**(47,768)**	**(95,690)**	**(14,820)**	**(80,748)**	**(192,882)**	**(29,874)**
Interest income	1,003	1,734	269	2,166	2,666	413
Interest expense	(490)	(1,412)	(219)	(696)	(2,647)	(410)
Other income	2,069	5	1	2,074	133	21
Foreign exchange loss, net	(99)	(803)	(124)	(20)	(1,101)	(170)
Others, net	(500)	(53)	(8)	(515)	(53)	(8)
Loss before income tax	**(45,785)**	**(96,219)**	**(14,901)**	**(77,739)**	**(193,884)**	**(30,028)**
Income tax expense	—	—	—	—	—	—
Net loss	**(45,785)**	**(96,219)**	**(14,901)**	**(77,739)**	**(193,884)**	**(30,028)**
Accretion of convertible redeemable preferred shares to redemption value	(17,311)	—	—	(28,050)	(1,989)	(308)
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	**(63,096)**	**(96,219)**	**(14,901)**	**(105,789)**	**(195,873)**	**(30,336)**
Other comprehensive loss						
Foreign currency translation adjustments, net of nil tax	(26)	(34,767)	(5,385)	3,498	(11,138)	(1,725)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	**(63,122)**	**(130,986)**	**(20,286)**	**(102,291)**	**(207,011)**	**(32,061)**
Weighted average number of ordinary shares used in per share calculation:						
—Basic	99,044,776	336,167,006	336,167,006	99,044,776	320,415,223	320,415,223
—Diluted	99,044,776	336,167,006	336,167,006	99,044,776	320,415,223	320,415,223
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders						
—Basic	(0.64)	(0.29)	(0.04)	(1.07)	(0.61)	(0.09)

—Diluted	(0.64)	(0.29)	(0.04)	(1.07)	(0.61)	(0.09)