# PRESS RELEASE

## Gracell Biotechnologies Reports Second Quarter 2023 Unaudited Financial Results and Provides Corporate Update

- *Commenced Phase 1b/2 clinical trial in U.S. evaluating FasTCAR-T GC012F for the treatment of relapsed/refractory multiple myeloma (RRMM) and patient screening underway in Phase 1b portion*
- *Expect to commence Phase 1/2 clinical trial in China evaluating GC012F for the treatment of RRMM in the third quarter of 2023*
- *On track to submit US IND filing for planned Phase 1 trial of GC012F in refractory systemic lupus erythematosus (rSLE) in 2023*
- *Dosed multiple patients in the investigator-initiated trial (IIT) in China evaluating GC012F in rSLE*
- *Closed a private placement of ordinary shares and warrants to generate $100 million upfront and up to $50 million tied to exercise of warrants, extending cash runway into the second half of 2026*
- *Management to host conference call at 8:00 a.m. ET today*

SAN DIEGO and SUZHOU, China and SHANGHAI, China, Aug. 14, 2023 (GLOBE NEWSWIRE) -- Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell" or the "Company"), a global clinical-stage biopharmaceutical company dedicated to developing innovative and highly efficacious cell therapies for the treatment of cancer and autoimmune diseases, today reported second quarter unaudited financial results for the period ended June 30, 2023, and provided corporate updates.

"We are delighted with the significant milestones achieved in the past few months across our reprioritized pipeline. Encouraged by the latest impressive clinical data for GC012F across hematological indications presented at ASCO and EHA, we continue to focus on the development and expansion of this highly-competitive, next-generation CAR-T product candidate. The Phase 1b part of the RRMM US IND trial has commenced as patient screening is underway. We also continue to explore the potential of GC012F in early line, and look forward to presenting longer follow-up data from the ongoing clinical IIT evaluating GC012F in newly diagnosed multiple myeloma (NDMM) at an upcoming international medical conference in September," said Dr. William (Wei) Cao, founder, Chairman and CEO of Gracell. "The expansion into the autoimmune diseases is also a priority and we are on track to file the US IND in 2023 to conduct a Phase 1 trial for GC012F in rSLE. We have dosed multiple patients in the rSLE IIT and anticipate that topline data from this ongoing study will be available during the first half of 2024."

Dr. Cao continued, "With the completion of a private placement financing of $100 million upfront and up to $50 million upon warrant exercise led by well-regarded healthcare investors, we strengthened our balance sheet and extended our runway into the second half of 2026."

**Pipeline Summary**

**FasTCAR-T GC012F:** Autologous BCMA/CD19 dual targeting CAR-T therapy candidate utilizing FasTCAR next-day manufacturing to significantly shorten patient wait times and enhance cell fitness

**FasTCAR-T GC012F in relapsed refractory multiple myeloma (RRMM):**

- Initiated the Company-sponsored Phase 1b/2 clinical trial in U.S. (NCT05850234) evaluating GC012F in RRMM
  - Patient recruitment has commenced in the Phase 1b part of the trial
- On track to initiate the Company-sponsored Phase 1/2 clinical trial in China evaluating GC012F in RRMM expected in the third quarter of 2023
- Presented long-term follow-up data from a multicenter IIT at ASCO 2023 Annual Meeting and EHA2023 Congress demonstrating deep and durable responses
  - Among 29 treated RRMM patients, GC012F showed 93.1% overall response rate (ORR), 82.8% stringent complete response (sCR) rate, 100% minimal residual disease negativity (MRD-), and a median progression free survival (mPFS) of 38.0 months (95% CI: 11.8-NR) as of the data cutoff date April 12, 2023

**FasTCAR-T GC012F in newly diagnosed multiple myeloma (NDMM):**

- Clinical data update with additional patients and longer follow-up from ongoing IIT to be presented in the third quarter of 2023

**FasTCAR-T GC012F in B-cell non-Hodgkin's lymphoma (B-NHL):**

- Presented updated clinical data from an IIT at ASCO 2023 Annual Meeting and EHA2023 Congress

- Among nine treated patients and as of the data cutoff date April 12, 2023, GC012F showed 100% ORR and 77.8% complete response (CR) rate at 3 months, and 66.7% CR rate at 6 months. All nine patients are classified as relapsed/refractory diffuse large B-cell lymphoma (DLBCL), the most challenging subtype of B-NHL.

**FasTCAR-T GC012F in refractory systemic lupus erythematosus (rSLE)**

- BCMA/CD19 dual-targeting design aims to achieve more effective elimination of antibody-secreting cells, in comparison to CD19 single-targeting CAR-T
- IIT evaluating GC012F in rSLE underway in China
  - Patient enrollment and dosing underway
  - Anticipate to share initial data in the first half of 2024
- On track to submit US IND filing for planned Phase 1 trial in 2023

**GC007g for the treatment of B-ALL**: Allogeneic CD19-targeted CAR-T cell therapy, derived from human leukocyte antigen (HLA) matched donor, for the treatment of relapsed/refractory b-cell acute lymphoblastic leukemia (r/r B-ALL) patients who failed transplant and may not be eligible for autologous CAR-T therapy.

- Phase 1 data presented at EHA2023 Congress highlighted 100% MRD- complete response or complete response with/without complete hematologic recovery (CR/CRi)
- Registrational Phase 2 trial ongoing in China

**SMART CART™ GC506:** 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.

- Commenced an IIT in China for GC506 in Claudin18.2 positive solid tumors

**Reprioritization of Pipeline:** The Company completed a strategic review of its clinical pipeline and will prioritize its resources on the clinical development of its most innovative product candidates that have the best-in-class potential, such as dual-targeting FasTCAR-T GC012F. The Company expects to incur minimal expenses related to program discontinuations.

**PIPE Financing**

On August 10, 2023, the Company closed a private placement of 138,900,000 ordinary shares (equivalent to 27,780,000 of the Company's American depositary shares ("ADSs")) and warrants to purchase up to 44,802,870 ordinary shares (equivalent to 8,960,574 ADSs), exercisable at the election of the investors within 24 months after closing. The Company has received $100 million in proceeds from the private placement of ordinary shares, and will receive up to an additional $50 million if the warrants are fully exercised. The financing included participation from the high-quality healthcare investors and was led by Vivo Capital, with participation from new and existing shareholders including Adage Capital Partners LP, Exome Asset Management, Janus Henderson Investors, Logos Capital, OrbiMed, Pivotal Life Sciences, RA Capital Management and TCGX, among others. The aggregate proceeds from this financing, combined with current cash, cash equivalents, is expected to be sufficient to fund the current operating plan into the second half of 2026.

**Financial Results for Second Quarter Ended June 30, 2023**

As of June 30, 2023, the Company had RMB1,188.0 million (US$163.8 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 RMB103.0 million (US$14.2 million) and long-term borrowings of RMB40.0 million (US$5.5 million).

Net loss attributable to ordinary shareholders for the three months ended June 30, 2023 was RMB146.9 million (US$20.3 million), compared to RMB146.3 million for the corresponding prior year period.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2023 were RMB103.8 million (US$14.3 million), compared to RMB117.1 million in the corresponding prior year period. The decrease was primarily due to the decreased spending on research, development, clinical trials and payroll.

Administrative Expenses

Administrative expenses for the three months ended June 30, 2023 were RMB37.4 million (US$5.2 million), compared to RMB28.8 million for the corresponding prior year period. The increase was primarily driven by an increase in professional service fees as well as an increase in share-based compensation expenses.

As of June 30, 2023, 340,655,139 ordinary shares (excluding 22,735,527 ordinary shares issued to depositary bank as of June 30, 2023, for bulk issuance of ADSs reserved for future issuances upon the exercise or vesting of awards granted under our share incentive plans), par value of US$0.0001 per share, were issued and outstanding. As of June 30, 2023, 19,529,166 options were granted and 14,852,668 options were outstanding, and 5,038,056 restricted share units ("RSUs") were granted under our employee stock option plan.

Immediately following the close of private placement transaction, 479,555,139 ordinary shares, par value of US$0.0001 per share, were issued and outstanding. Each of our ADS represents five ordinary shares.

**Conference Call and Webcast Details:**
Monday, August 14, 2023 @ 8:00 am ET
Investor domestic dial-in: (800) 715-9871
Investor international dial-in: (646) 307-1963
Conference ID: 2527305

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 GC012F**
GC012F is Gracell's FasTCAR-enabled BCMA/CD19 dual-targeting autologous CAR-T cell therapy, which aims to transform cancer and autoimmune disease treatment by driving fast, deep and durable responses with improved safety profile. GC102F is currently being evaluated in clinical studies in multiple hematological cancers as well as autoimmune diseases, and has demonstrated a consistently strong efficacy and safety profile. Gracell has initiated a Phase 1b/2 trial evaluating GC012F for the treatment of relapsed/refractory multiple myeloma in the US and expects to initiate a Phase 1/2 clinical trial in China. Gracell has also commenced an investigator-initiated trial evaluating GC012F for the treatment of refractory systemic lupus erythematosus (rSLE).

**About FasTCAR**
Introduced in 2017, FasTCAR is Gracell's revolutionary next-day autologous CAR-T cell manufacturing platform. FasTCAR is designed to lead the next generation of cell therapy for cancer and autoimmune diseases, and improve outcomes for patients by enhancing CAR-T cell fitness, reducing costs, and enabling more patients to access critical CAR-T treatment. FasTCAR drastically shortens cell production from weeks to overnight, potentially reducing patient wait times and probability for their disease to progress. Furthermore, FasTCAR T-cells appear younger than traditional CAR-T cells, making them more proliferative and effective at killing cancer cells. In November 2022, FasTCAR was named the winner of the Biotech Innovation category of the 2022 Fierce Life Sciences Innovation Awards for its ability to address major industry obstacles.

**About Gracell**
Gracell Biotechnologies Inc. ("Gracell") is a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies for the treatment of cancers and autoimmune diseases. Leveraging its innovative FasTCAR and TruUCAR technology platforms and SMART CAR™ 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 and autoimmune diseases. The lead candidate BCMA/CD19 dual-targeting FasTCAR-T GC012F is currently being evaluated in the clinical studies for the treatment of multiple myeloma, B-NHL and systemic lupus erythematosus (SLE). For more information on Gracell, please visit www.gracellbio.com and follow @GracellBio on LinkedIn.

**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 7.2513 to US$1.00, the rate in effect as of June 30, 2023 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 U.S. 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 December 31, | As of June 30, |
|---|---|

| | 2022 | 2023 | |
|---|---|---|---|
| | RMB | RMB | US$ |
| **ASSETS** | | | |
| **Current assets:** | | | |
| Cash and cash equivalents | 1,454,645 | 1,184,430 | 163,340 |
| Short-term investments | 3,559 | 3,574 | 493 |
| Prepayments and other current assets | 37,551 | 59,402 | 8,192 |
| **Total current assets** | **1,495,755** | **1,247,406** | **172,025** |
| Property, equipment and software, net | 123,126 | 106,698 | 14,714 |
| Operating lease right-of-use assets | 21,546 | 12,896 | 1,778 |
| Other non-current assets | 15,849 | 10,886 | 1,501 |
| **TOTAL ASSETS** | **1,656,276** | **1,377,886** | **190,018** |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | | |
| **Current liabilities:** | | | |
| Accruals and other current liabilities | 85,991 | 75,580 | 10,422 |
| Short-term borrowings | 104,600 | 90,000 | 12,412 |
| Operating lease liabilities, current | 17,545 | 12,472 | 1,720 |
| Amounts due to a related party | 4,662 | 2,760 | 381 |
| Current portion of long-term borrowings | 7,844 | 13,004 | 1,793 |
| **Total current liabilities** | **220,642** | **193,816** | **26,728** |
| Operating lease liabilities, non-current | 6,485 | 2,542 | 351 |
| Long-term borrowings | 46,505 | 39,958 | 5,510 |
| Other non-current liabilities | 6,879 | 4,851 | 669 |
| **TOTAL LIABILITIES** | **280,511** | **241,167** | **33,258** |
| **Shareholders' equity:** | | | |
| Ordinary shares | 223 | 225 | 31 |
| Additional paid-in capital | 2,927,295 | 2,942,348 | 405,768 |
| Accumulated other comprehensive income | 73,528 | 118,089 | 16,285 |
| Accumulated deficit | (1,625,281) | (1,923,943) | (265,324) |
| **Total shareholders' equity** | **1,375,765** | **1,136,719** | **156,760** |
| **TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY** | **1,656,276** | **1,377,886** | **190,018** |

**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, | | |
|---|---|---|---|---|---|---|
| | 2022 | 2023 | | 2022 | 2023 | |
| | RMB | RMB | US$ | RMB | RMB | US$ |
| **Expenses** | | | | | | |
| Research and development expenses | (117,058) | (103,803) | (14,315) | (238,895) | (241,309) | (33,278) |
| Administrative expenses | (28,766) | (37,350) | (5,151) | (66,656) | (66,438) | (9,162) |
| **Loss from operations** | **(145,824)** | **(141,153)** | **(19,466)** | **(305,551)** | **(307,747)** | **(42,440)** |
| Interest income | 2,702 | 5,268 | 726 | 5,198 | 19,895 | 2,744 |
| Interest expense | (1,657) | (1,704) | (235) | (3,082) | (3,360) | (463) |
| Other income | 1,797 | 5,907 | 815 | 1,940 | 6,538 | 902 |
| Foreign exchange loss, net | (3,324) | (11,017) | (1,519) | (3,395) | (9,736) | (1,343) |
| Others, net | 1 | (4,225) | (583) | 2 | (4,226) | (583) |
| **Loss before income tax** | **(146,305)** | **(146,924)** | **(20,262)** | **(304,888)** | **(298,636)** | **(41,183)** |
| Income tax expense | — | (10) | (1) | — | (26) | (4) |
| **Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders** | **(146,305)** | **(146,934)** | **(20,263)** | **(304,888)** | **(298,662)** | **(41,187)** |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Other comprehensive income** | | | | | | |
| Foreign currency translation adjustments, net of nil tax | 82,028 | 62,443 | 8,611 | 75,591 | 44,561 | 6,145 |
| **Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders** | **(64,277)** | **(84,491)** | **(11,652)** | **(229,297)** | **(254,101)** | **(35,042)** |
| **Weighted average number of ordinary shares used in per share calculation:** | | | | | | |
| —Basic | 338,355,742 | 341,336,375 | 341,336,375 | 338,244,214 | 339,951,916 | 339,951,916 |
| —Diluted | 338,355,742 | 341,336,375 | 341,336,375 | 338,244,214 | 339,951,916 | 339,951,916 |
| **Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders** | | | | | | |
| —Basic | (0.43) | (0.43) | (0.06) | (0.90) | (0.88) | (0.12) |
| —Diluted | (0.43) | (0.43) | (0.06) | (0.90) | (0.88) | (0.12) |

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