



## Gracell Biotechnologies Reports Fourth Quarter and Fiscal Year 2020 Unaudited Financial Results and Provides Corporate Update

*Reported interim readouts for lead CAR-T product candidates: FasTCAR-enabled dual-targeting BCMA/CD19 autologous CAR-T product candidate GC012F for the treatment of multiple myeloma and TruUCAR-enabled CD7-directed CAR-T product candidate GC027 for the treatment of T-ALL*

*Completed initial public offering of ADSs for net proceeds of \$220 million (USD); approximately \$338 million\* in cash as of January 31, 2021*

*Conference call tomorrow, March 10, 2021 at 8:00 am ET*

SUZHOU and SHANGHAI, China, March 09, 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, today reported its unaudited financial results for the fourth quarter and fiscal year ended December 31, 2020 and recent business highlights. Gracell will host a conference call tomorrow, Wednesday, March 10, at 8:00 am Eastern Time.

"We are very pleased with the substantial progress made thus far in 2021 and over the course of 2020. We recently closed a successful initial public offering that was supported by top-tier institutional investors. We believe their support reflects confidence in our proprietary FasTCAR and TruUCAR platforms that enable highly differentiated autologous and allogeneic CAR-T therapies," commented Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. "Our lead asset GC012F, a FasTCAR-enabled dual-targeting BCMA/CD19 CAR-T cell therapy, currently being studied in multiple myeloma, has shown promising results including high risk patients. We were thrilled to present results from an interim analysis at last year's American Society of Hematology (ASH) Annual Meeting. We look forward to providing further updates at upcoming scientific meetings."

"Following the success of our recent business developments, the Gracell team continues to feel energized as we work towards accomplishing our operational goals for 2021. Looking ahead, we are well-positioned to continue to fund our R&D programs and expansion of operations in China and the U.S. We have just recently received IND approval in China for GC019F, a FasTCAR-enabled CD19-targeted CAR-T therapy for the treatment of B-ALL, and we believe this is a validation of our next-day manufacturing FasTCAR platform. We look forward to sharing updates of our lead programs at major medical conferences. To support our clinical operations, we plan to establish R&D capabilities in the U.S. and to significantly expand our GMP manufacturing facility in China during 2021 and beyond. With tremendous energy and dedication, we will continue to strive towards advancing our innovative CAR-T pipeline for difficult to treat cancers while driving further value for our shareholders," concluded Dr. Cao.

\* Translation from Renminbi to U.S. dollars of cash balance on January 31, 2021 is for the convenience of the reader and made at a rate of RMB6.4709 to US\$1.00, the rate in effect as of January 31, 2021.

### 2020 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.*

- An interim data readout was presented as an oral presentation at the ASH's 2020 Annual Meeting (Press Release [Dec 2020](#))
- As of July 17, 2020, the study had enrolled and treated 16 patients at three dose levels with the highest dose level at  $3 \times 10^5$  cells/kg. Notably, the vast majority of this study population (93.8%) belong to a subgroup of MM patients with high-risk features, a difficult to treat patient population. Overall Response Rate (ORR) at time of data cut off was 93.8% with responses being VGPR or better. 100% of the patients treated at the highest dose level (n=6) achieved minimal residual disease negative stringent complete response (MRD- sCR) that was maintained through a landmark analysis at six months (n=4). GC012F showed a favorable safety profile with primarily low grade cytokine release syndrome (CRS) (14 out of 16 patients (87.5%) Grade 1/2, 2 (12.5%) patients Grade 3, no Grade 4 or 5) and no patients experienced any immune effector cell-associated neurotoxicity syndrome (ICANS)

#### **GC019F for the treatment of with B-cell acute lymphoblastic leukemia (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](#))

#### **GC027 for the treatment of adult T cell acute lymphoblastic leukemia (T-ALL):**

*GC027 is a TruUCAR-enabled allogeneic CD7-targeted 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.*

- Preliminary efficacy and safety data were presented as oral presentations at AACR (the American Association for Cancer Research) Virtual Annual Meeting 2020 (Press Release [April 2020](#)) and EHA (European Hematology Association) 25<sup>th</sup> Annual Congress 2020.
- As of February 2020, the study had enrolled and treated five patients who had failed a median of five prior-lines of therapy. All five evaluable patients achieved a response, CR or CRi, including four patients, or 80%, achieving MRD- CR on Day 28 after treatment. Four out of five patients experienced CRS of Grade 3 and one out of five patients experienced CRS of Grade 4. No patients developed ICANS or graft-versus-host-disease (GvHD)

#### **GC007g for the treatment of B-ALL:**

*GC007g is a donor-derived allogeneic CD19-targeted 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.*

- China's NMPA approved a pivotal seamless Phase 1/2 clinical trial for GC007g. (Press Release [Jan 2021](#)) The study is ongoing and accruing patients

#### **Corporate Highlights:**

- Expanded executive leadership team with appointments of Chief Medical Officer Dr. Martina Sersch, M.D., and Chief Financial Officer Dr. Kevin Xie, both bringing extensive knowledge and leadership experience to Gracell (Press Release [July 2020](#))
- Secured \$100 million in Series C funding in a round led by Wellington Management Company, OrbiMed and Morningside Ventures, and joined by Vivo Capital. Existing investors Temasek Holdings, Lilly Asia Ventures, and King Star Med LP also participated (Press Release [Oct 2020](#))
- Completed a successful initial public offering of American Depositary Shares (ADSs), raising net proceeds of approximately \$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 (JSMPA, Jiangsu is a province/state in China) for the production of CAR-T cell therapy products (Press Release [Jan 2021](#))

#### **Financial Results for the Fourth Quarter Ended December 31, 2020**

Research and development expenses for the three months ended December 31, 2020 were RMB60.7 million (US\$9.3 million), as compared to RMB38.0 million in the corresponding prior year period. This increase was primarily driven by increases of RMB10.4 million (US\$1.6 million) in costs incurred to advance preclinical and clinical pipeline as well as increases of RMB7.4 million (US\$1.1 million) and RMB 1.4 million (US\$0.2 million) in depreciation expenses of manufacturing facilities and labor costs, respectively.

Administrative expenses for the three months ended December 31, 2020 were RMB24.8 million (US\$3.8 million), compared to RMB7.9 million for the corresponding prior year period. This increase was primarily related to an increase of RMB11.4 million (US\$ 1.7 million) of professional service fees and also an increase of RMB4.9 million (US\$0.8 million) attributable to the expansion of administrative functions to support research and development activities.

Interest income for the fourth quarter of 2020 was RMB0.5 million (US\$0.07 million) as compared to RMB1.4 million for the corresponding prior year period. Other income for the fourth quarter of 2020 was RMB2.9 million (US\$0.4 million) as compared to RMB1.3 million for the corresponding prior year period.

Foreign exchange loss for the three months ended December 31, 2020 was RMB0.7 million (US\$0.1 million), compared to a foreign exchange gain of RMB0.4 million for the corresponding prior year period. This change in the foreign exchange gain of RMB1.1 million was primarily attributable to increase in United States dollars received along with the issuance of Series C convertible redeemable preferred shares and less favorable foreign exchange rate fluctuation during the quarter ended December 31, 2020.

Net loss attributable to ordinary shareholders for the three months ended December 31, 2020 was RMB99.9 million (US\$15.3 million), compared to RMB53.4 million for the corresponding prior year period.

#### **Financial Results for the Fiscal Year Ended December 31, 2020**

Research and development expenses for the year ended December 31, 2020 were RMB168.8 million (US\$25.9 million) compared to RMB119.2 million for the year ended December 31, 2019. This increase was primarily due to increases of RMB21.9 million (US\$3.4 million) in manufacturing and other costs to support the progression of our preclinical studies and clinical trials, an increase of RMB5.3

million (US\$0.8 million) in payroll and other personnel expenses related to expanded research and development headcount, and an increase of RMB17.1 million (US\$2.6 million) in depreciation expenses of manufacturing facilities.

Administrative expenses for the year ended December 31, 2020 were RMB45.6 million (US\$7.0 million) as compared to RMB27.4 million for the year ended December 31, 2019. This increase was primarily due to an increase of RMB12.2million (US\$1.9 million) in professional service fees and an increase of RMB4.5 million (US\$0.7 million) in personnel costs attributable to the expansion of administrative functions.

Interest income for the year ended December 31, 2020 was RMB2.9 million (US\$0.4 million) as compared to RMB3.9 million for the year ended December 31, 2019. Other income for the year ended December 31, 2020 was RMB4.7 million (US\$0.7 million), compared to RMB1.4 million for the year ended December 31, 2019.

Foreign exchange loss for the year ended December 31, 2020 was RMB2.9 million (US\$0.4 million), compared to a foreign exchange gain of RMB2.6 million for the year ended December 31, 2019. This decrease in the foreign exchange gain of RMB5.5 million was primarily attributable to increase in United States dollars received along with the issuance of Series C convertible redeemable preferred shares and less favorable foreign exchange rate fluctuation during the year ended December 31, 2020.

Net loss attributable to ordinary shareholders for the year ended December 31, 2020 was RMB274.6 million (US\$42.1 million), compared to RMB200.9 million for the year ended December 31, 2019.

#### *Balance Sheet Highlights*

As of December 31, 2020, we had RMB773.1 million (US\$118.5 million) in cash and cash equivalents and short-term investments. Subsequent to December 31, 2020, 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. The net proceeds to the Company were approximately US\$220 million (including in connection with the underwriters' exercise of their option to purchase additional ADSs in full).

In addition, as of December 31, 2020, the Company had short-term borrowings and current portion of long-term borrowings of RMB50.0 million (US\$7.7 million) and long-term borrowings of RMB51.9 million (US\$8.0 million).

#### **Conference Call Details**

*Wednesday, March 10, 2021 at 8:00 am ET*

Investor domestic dial-in: 877-407-0784

Investor international dial-in: 201-689-8560

Conference ID: 13716516

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](https://ir.gracellbio.com) for 90 days following the completion of the call.

#### **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 (22 to 36 hours), 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 as well as graft vs host disease (GvHD) without the need of being co-administered with immunosuppressive antibody 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.

#### **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 RMB6.5250 to US\$1.00, the rate in

effect as of December 31, 2020 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," "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: the clinical results of our product candidates, actions of regulatory agencies, which may affect the initiation, timing and progress of our clinical trials and marketing approval, our ability to achieve commercial success if any of our product candidates is approved, our ability to obtain and maintain protection of intellectual property for our product candidates and technology platforms, the future developments of the COVID-19 outbreaks, and other factors more fully discussed in the "Risk Factors" section of the final prospectus filed with the Securities and Exchange Commission (the "SEC") and in any subsequent filings made by the Company with the SEC. 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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### GRACELL BIOTECHNOLOGIES INC.

#### CONSOLIDATED BALANCE SHEETS AS OF DECEMBER 31, 2019 AND 2020

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

	As of December 31,				
	2019	2020		2020	
	RMB	RMB	US\$	RMB	US\$
	(Pro forma) (Note 1)				
<b>ASSETS</b>					
<b>Current assets:</b>					
Cash and cash equivalents	312,058	754,308	115,603	754,308	115,603
Short-term investments	4,200	18,743	2,872	18,743	2,872
Prepayments and other current assets	24,095	42,418	6,501	42,418	6,501
<b>Total current assets</b>	<b>340,353</b>	<b>815,469</b>	<b>124,976</b>	<b>815,469</b>	<b>124,976</b>
Property, equipment and software	48,323	119,083	18,250	119,083	18,250
Other non-current assets	23,541	30,398	4,658	30,398	4,658
<b>TOTAL ASSETS</b>	<b>412,217</b>	<b>964,950</b>	<b>147,884</b>	<b>964,950</b>	<b>147,884</b>
<b>LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT</b>					
<b>Current liabilities:</b>					
Short-term borrowings	—	49,990	7,661	49,990	7,661
Current portion of long-term borrowings	—	970	149	970	149
Accruals and other current liabilities	18,166	42,401	6,498	42,401	6,498
<b>Total current liabilities</b>	<b>18,166</b>	<b>93,361</b>	<b>14,308</b>	<b>93,361</b>	<b>14,308</b>
Long-term borrowings	—	51,926	7,958	51,926	7,958
Convertible loans	138,695	—	—	—	—
<b>TOTAL LIABILITIES</b>	<b>156,861</b>	<b>145,287</b>	<b>22,266</b>	<b>145,287</b>	<b>22,266</b>

#### Commitments and contingencies

#### Mezzanine equity:

Series A convertible redeemable preferred shares (US\$ 0.0001 par value; 31,343,284 shares authorized, issued and outstanding as of December 31, 2019 and 2020; and nil outstanding on a pro forma basis as of December 31, 2020)	82,334	110,468	16,930	—	—
Series B-1 convertible redeemable preferred shares (US\$ 0.0001 par value; nil and 21,735,721 shares authorized, issued and outstanding as of December 31, 2019 and 2020 respectively; and nil outstanding on a pro forma basis as of December 31, 2020)	—	142,481	21,836	—	—
Series B-2 convertible redeemable preferred shares (US\$ 0.0001 par value; 59,327,653 shares authorized, issued and outstanding as of December 31, 2019 and 2020; and nil outstanding on a pro forma basis as of December 31, 2020)	465,509	495,799	75,985	—	—
Series C convertible redeemable preferred shares (US\$ 0.0001 par value; nil and 61,364,562 shares authorized, issued and outstanding as of December 31, 2019 and 2020 respectively; and nil outstanding on a pro forma basis as of December 31, 2020)	—	658,788	100,963	—	—
<b>Total mezzanine equity</b>	<b>547,843</b>	<b>1,407,536</b>	<b>215,714</b>	<b>—</b>	<b>—</b>
<b>Shareholders' deficit:</b>					
Ordinary shares(par value of US\$0.0001 per share; 500,000,000 and 500,000,000 shares authorized; 99,044,776 shares issued and outstanding as of December 31, 2019 and 2020; 272,815,996 shares issued and outstanding on a pro forma basis as of December 31, 2019 (unaudited))	68	68	10	181	28
Additional paid-in capital	—	—	—	1,407,423	215,696
Accumulated other comprehensive loss	(3,159)	(23,912)	(3,665)	(23,912)	(3,665)
Accumulated deficit	(289,396)	(564,029)	(86,441)	(564,029)	(86,441)
<b>Total shareholders' deficit</b>	<b>(292,487)</b>	<b>(587,873)</b>	<b>(90,096)</b>	<b>819,663</b>	<b>125,618</b>
<b>TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT</b>	<b>412,217</b>	<b>964,950</b>	<b>147,884</b>	<b>964,950</b>	<b>147,884</b>

Note 1: The unaudited pro forma balance sheet information as of December 31, 2020 assumes the automatic conversion of all of the outstanding convertible preferred shares into ordinary shares at a conversion ratio of 1:1, as if the conversion had occurred as of December 31, 2020.

## GRACELL BIOTECHNOLOGIES INC.

### CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

#### FOR THE YEARS ENDED DECEMBER 31, 2018, 2019 AND 2020

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

	For the years ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US\$
<b>Expenses</b>				
Research and development expenses	(52,243)	(119,218)	(168,830)	(25,874)
Administrative expenses	(10,261)	(27,362)	(45,566)	(6,983)
<b>Loss from operations</b>	<b>(62,504)</b>	<b>(146,580)</b>	<b>(214,396)</b>	<b>(32,857)</b>
Interest income	1,435	3,932	2,870	440
Interest expense	—	—	(2,155)	(330)
Other income	256	1,449	4,707	721
Foreign exchange gain, net	—	2,556	(2,914)	(447)
Others, net	20	(21)	(12)	(2)
<b>Loss before income tax</b>	<b>(60,793)</b>	<b>(138,664)</b>	<b>(211,900)</b>	<b>(32,475)</b>
Income tax expense	—	—	—	—
<b>Net loss</b>	<b>(60,793)</b>	<b>(138,664)</b>	<b>(211,900)</b>	<b>(32,475)</b>
Deemed dividend to convertible redeemable preferred shareholders	—	(25,390)	—	—
Accretion of convertible redeemable preferred shares to redemption value	(12,199)	(36,802)	(62,733)	(9,614)

<b>Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>	<b>(72,992)</b>	<b>(200,856)</b>	<b>(274,633)</b>	<b>(42,089)</b>
<b>Other comprehensive loss</b>				
Foreign currency translation adjustments, net of nil tax	—	(3,159)	(20,754)	(3,181)
<b>Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>	<b>(72,992)</b>	<b>(204,015)</b>	<b>(295,387)</b>	<b>(45,270)</b>
<b>Weighted average number of ordinary shares used in per share calculation:</b>				
—Basic	100,089,552	99,053,363	99,044,776	99,044,776
—Diluted	100,089,552	99,053,363	99,044,776	99,044,776
<b>Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>				
—Basic	(0.73)	(2.03)	(2.77)	(0.42)
—Diluted	(0.73)	(2.03)	(2.77)	(0.42)