**PRESS RELEASE**

# Gracell Biotechnologies Receives Medical Products Manufacturing Certificate for CAR-T Cell Therapy Products

SUZHOU, China, January 15, 2021 -- Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell"), a global clinical-stage biopharmaceutical company dedicated to developing highly efficacious and affordable cell therapies for the treatment of cancer, has been granted the Medical Products Manufacturing Certificate (MPMC) from the Jiangsu Medical Products Administration (JSMPA, Jiangsu is a province/state in China) for its CAR-T cell therapy products. The certification was granted on January 4, 2021, and indicates that Gracell's site in Suzhou Industrial Park（SIP) has fully met the compliance requirements for Good Manufacturing Practice (GMP) in relation to the production of CAR-T cell therapy for cancer treatment.

Since the new Pharmaceutical Administration Law of the People's Republic of China took effect on December 1, 2019, GMP certification has been abolished in China and applications for GMP certification are no longer accepted by the National Medical Products Administration (NMPA). Instead, the "Measures for Supervision and Management of Medical Products Manufacturing", which came into effect on July 1, 2020, clearly outlines strict and detailed requirements regarding permissions and relevant supervisions for the manufacture of medical products. Only manufacturing sites that fully satisfy these stringent requirements can successfully pass an on-site inspection to obtain the "Medical Products Manufacturing Certificate".

As of March 2020, Gracell has implemented a comprehensive Quality Management System that fully complies with the U.S. FDA cGMP, EU GMP, China GMP, and relevant global guidelines for cell therapy products.

Gracell's Suzhou site underwent and successfully passed an on-site inspection conducted by JSMPA inspectors in November, 2020, and received its official "Medical Products Manufacturing Certificate" on January 4, making it one of five CAR-T cell therapy manufacturers nationwide to receive the license.

"Our passion is to change the way conventional CAR-T therapies have been manufactured, and provide effective, low cost manufacturing of cellular gene therapeutics with fast turnaround time," said Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. "We are thrilled to receive this certificate from JSMPA, which will enable us to further advance our current clinical programs including our FasTCAR-T programs and bring transformative CAR-T cell therapies to a broader group of patients."

**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.

**Cautionary Noted 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,” “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 uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all, and other factors discussed in the “Risk Factors” section of the preliminary prospectus filed 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.

**Media contact**

**Linc He**

Linc.he@gracellbio.com

**Investor contact**

**Gracie Tong**

Gracie.tong@gracellbio.com