



Gracell Biotechnologies Signs Exclusive License Agreement with FutureGen Biopharm to Develop Engineered Immune Cell Therapies Targeting Claudin 18.2 in Solid Tumors

SUZHOU and SHANGHAI, China, and PALO ALTO, Calif., Aug. 16, 2021 /PRNewswire/ -- 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, today announced an exclusive license agreement with FutureGen Biopharm ("FutureGen"), an innovative biopharmaceutical company, to develop engineered immune cell therapies targeting Claudin 18.2 ("CLDN18.2") in solid tumors.



The collaboration aims to leverage Gracell's extensive experience in immune cell therapy in synergy with FutureGen's fully human CLDN18.2 antibodies to develop, manufacture and commercialize novel immune cell therapies for the treatment of patients with CLDN18.2 positive cancers.

CLDN18.2 is a tumor-specific marker that is overexpressed in a variety of tumor tissues, including in gastric or gastroesophageal junction cancers, pancreatic cancers and esophageal cancers, but rarely expressed in normal human tissues. This feature supports the therapeutic potential of CLDN18.2 as a key target for immune cell therapies. In particular, gastric cancer (around 70%^[1] CLDN18.2 expression) is among the most frequently diagnosed malignancies worldwide and the second leading cause of cancer-related death. An estimated 1,033,701 new cases and 782,685 deaths occurred in 2018^[2], representing a highly unmet medical need in treating gastric cancer.

"Gracell has been making significant progress in developing innovative CAR-T therapies for solid tumors as well as hematological malignancies," Dr. William (Wei) Cao, Founder, Chairman and Chief Executive Officer of Gracell said. "This partnership with FutureGen marks another key milestone in our persistent efforts for treating solid tumors. Moving forward, we expect to explore more strategic alliances to identify additional targets that maximize the value of our highly differentiated technology platforms and eventually benefit cancer patients worldwide."

"Gracell has been optimizing its proprietary Enhanced CAR technology to improve CAR-T cell persistence and efficacy in solid tumors. The preliminary clinical investigator-initiated trial data of our first generation Enhanced CAR-T for solid tumors has shown tolerability and preliminary efficacy. These initial results have been accepted to be published soon in *Cellular & Molecular Immunology*," said Dr. Lianjun Shen, Senior Vice President, Head of Research and Development at Gracell. "We are very excited to partner with FutureGen to develop next generation immune cell therapies against CLDN18.2-expressing malignancies, and hope to unlock significant potential of our next generation Enhanced CAR-T therapies for solid tumors, one of our founding missions."

Dr. Zhaoyu Jin, the Founder and Chief Executive Officer of FutureGen said, "The specific CLDN18.2 antibody has been developed through our innovative STEP and CAP technology platforms. The fine-tuned affinity of antibody for CAR-T application may eliminate CLDN18.2 positive tumor cells more specifically with better safety profile. We are very excited to collaborate with Gracell, a lead company in the cell and gene therapy industry, to leverage their innovative Enhanced CAR-T technology platform and experience in the field and our proprietary cutting-edge technologies to develop advanced treatments across solid tumors."

Under the terms of the agreement, FutureGen will receive an upfront payment and will be eligible to receive additional payments based on the achievement of non-clinical validation, clinical development and commercialization milestones, as well as low single-digit royalties.

About CLDN18.2

CLDN18.2, a small transmembrane protein with four transmembrane domains and two extracellular loops, is overexpressed in a significant proportion of gastric cancers and esophageal adenocarcinomas. The restricted expression makes it a promising target for the treatment of gastric or gastroesophageal junction cancers, pancreatic cancers, etc. Overall, CLDN18.2 is prevalently expressed in the cancer tissues of approximately 70% of gastric cancer patients and approximately 60% of pancreatic cancer patients. CLDN18.2-specific antibodies developed to target CLDN18.2 have exhibited anti-tumor activity in preclinical studies.^[3]

About Enhanced CAR

Enhanced CAR is Gracell's proprietary technology that further strengthens the functionality of CAR-T cells, for example by overcoming the immunosuppressive tumor micro-environment (TME) and/or increasing cytokine signaling. Gracell utilizes gene editing technologies to edit some check point inhibitor(s) or/and cytokine(s) or cytokine receptor(s) on CAR-T cells to release potential suppression from tumor cells and other suppressive immune cells in tumor tissue to enhance CAR-T cells' functionality. Our second generation Enhanced CAR technology can be implemented to many other targets in several types 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, 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. Follow @GracellBio on [LinkedIn](#).

About FutureGen

FutureGen Biopharm ("FutureGen") focuses on precise cancer immunotherapy and drives the development of novel therapeutics through the world's leading antibody engineering technology. The company has developed a Structure-based Targeted Evolution Platform ("STEP") and Cell-based Antibody Panning ("CAP") for antibody discovery and engineering with proprietary intellectual property rights, which can quickly and efficiently screen and optimize a series of candidate drugs that have the potential to be best-in-class antibodies with specific epitopes, ideal affinity and activity, and finest developability. Currently, the ADCC enhanced CLDN18.2 antibody for gastric cancer and pancreatic cancer is at the clinical trial stage, and multiple bispecific therapeutic antibodies are at pre-clinical stage. For more information on FutureGen Biopharm, please visit <http://www.futuregen.com.cn/>.

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 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.

[1] Clinical Implications of Claudin18.2 Expression in Patients With Gastric Cancer

[2] Hsu A, Chudasama R, Almhanna K, Raufi A. Targeted therapies for gastroesophageal cancers. *Ann. Transl. Med.* (2020) 8:1104. doi: 10.21037/atm-20-3265

[3] The full-length Claudin 18.2 to accelerate antibody drug development

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