

News Release

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Merck KGaA, Darmstadt, Germany Announces Collaboration with GenScript to Accelerate Cell and Gene Therapy Industrialization in China

- **Collaboration to build global-standard platform for plasmid and virus manufacturing in China**
- **Company plans to provide comprehensive products, services and training to GenScript on manufacturing capability development**

Darmstadt, Germany, March 19, 2019 – Merck KGaA, Darmstadt, Germany, a leading science and technology company and leader in genome editing, today announced the signing of a non-binding Memorandum of Understanding with [GenScript](#) for a strategic alliance focusing on plasmid and viral vector manufacturing.

“Manufacturing of high-quality plasmid and viral vectors is one of the most critical components in the commercialization of cell and gene therapy,” said Udit Batra, member of the Executive Board and CEO, Life Science at Merck KGaA, Darmstadt, Germany. “As we are one of the world’s largest manufacturers of viral vectors, this collaboration will give GenScript access to our leading experience of nearly three decades of experience in gene and cell therapy manufacturing.”

“We are excited about the planned collaboration with Merck KGaA, Darmstadt, Germany to better serve our local and overseas customers with cGMP manufacturing facilities, and to accelerate the drug commercialization process,” said Daniel Wang Dongliang, vice president of Operations, Biologics Development Business Unit, at GenScript.

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The parties envision an alliance that will accelerate the industrialization and commercialization of cell and gene therapy in China. GenScript, a leading biotech company headquartered in Nanjing, China, aims to create a global-standard platform of plasmid and virus manufacturing service in the country. Merck KGaA, Darmstadt, Germany plans to provide GenScript with comprehensive products, training and consulting services covering process design, facility concept design and quality management system set-up from lab development to large-scale GMP manufacturing.

Merck KGaA, Darmstadt, Germany is among only a few manufacturers that have an industrialized process to make viral vectors. To create personalized therapy products, genes are delivered into immune cells using viral vectors, such as the ones that the company produces. It offers a unique combination as a contract manufacturing organization, serving other companies to provide services, and as a bioprocess manufacturing equipment maker.

A confluence of demand, growth and subsequent need to scale the cell and gene therapy market in China is an important driver for Merck KGaA, Darmstadt, Germany to deliver its expertise to this region. According to clinicaltrials.gov, China is the world-leader in terms of where gene-modified cell therapy clinical trials are conducted. Today, more than 130 companies in China are developing cell and gene therapies ranging from chimeric antigen receptor T cell therapy (CAR-T) / T cell receptor therapy (TCR-T) and *adeno-associated virus* (AAV) to oncolytic virus¹. Moreover, 28 cell and gene therapy Investigational New Drug (IND) applications² were submitted in China between Dec. 2017 – Dec. 2018 with more than a third already approved for clinical trials.

Merck KGaA, Darmstadt, Germany plans to provide a complete set of process products, services and staff training to support GenScript in building a world-class plasmid and viral vector manufacture platform to accelerate the industrialization of cell and gene therapy in China.

References

- 1) HSmap report 2017 – Chinese Gene Therapy Industry Atlas
- 2) - Source: Yaozhi database

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About GenScript

GenScript Biotech Corp. is a world leader in the biological reagent service industry. Headquartered in Nanjing, China, the Group currently has a couple of R&D, production and operation centers in Nanjing and New Jersey, two production bases in Zhenjiang and Jinan, two European bases for its subsidiary Legend in Netherlands and Ireland, and a wholly-owned subsidiary in Japan.

With the fast growth in developing biological reagents, the Company now expands its business into immunotherapy, contract development and manufacturing organization (CDMO), lab equipment and industrial microbiology applications. To support these businesses, it has established open and innovation-driven technological platforms, GMP facilities for pre-clinical drug discovery and pharmaceutical product development and a full-range industrial microbial R&D and industrialization platform for enzyme screening, GMP plasmid and virus production, antibody drug discovery (Bispecific antibodies technology; Hybridoma technology; Humanized Antibody technology; Phage display technology), genetic engineering, protein engineering and fermentation process optimization. The Company is uniquely positioned and well equipped to further fulfill its mission in making people and nature healthier through biotechnology.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 52,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From advancing gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2018, Merck KGaA, Darmstadt, Germany, generated sales of €14.8 billion in 66 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials. Since its founding 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.