

News Release

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Merck KGaA, Darmstadt, Germany Announces Boost to Commercial Viral Vector and Gene Therapy Manufacturing Capacity

- **New, € 100 million facility will more than double existing production capacity**
- **Supports large-scale commercial manufacturing of viral and gene therapy products**

Darmstadt, Germany, April 21, 2020– Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced a second Carlsbad, California-based facility for the [BioReliance® viral and gene therapy service offering from its Life Science business](#). The new, € 100 million commercial facility is expected to open next year.

“Viral vector manufacturing has transitioned from a niche industry to the cornerstone of the future of biopharmaceuticals,” said Udit Batra, member of the Executive Board and CEO, Life Science business of Merck KGaA, Darmstadt, Germany. “Few companies have the scale and quality systems in place for manufacturing commercial viral vector products. Building on our success in helping customers commercialize their gene therapies made possible by viral vectors, our expansion will help innovators produce at a scale that ensures these therapies reach more patients in need.”

The company’s Life Science business facility in Carlsbad, California manufactures gene therapies for its customers globally. Gene therapy involves the delivery of a genetic payload into patient cells to produce a therapeutic effect such as correction



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of a mutated gene or retargeting of an immune cell to fight cancer. Diseases such as hemophilia and cancer are being investigated using this technique where a single dose may cure the disease. Viral vectors are often called the most complex therapeutic manufactured today. The gene therapy market, which accounted for \$ 1 billion in 2018, is expected to reach \$ 10 billion by 2026, according to a [recent Biotech Forecasts global market analysis and industry forecast](#).

The new, 140,000-square-foot manufacturing facility will support viral and gene therapy production at the 1000-liter scale using the [Mobius® single-use equipment from the company's Life Science business](#). The site is part of the Life Science business' expanding product and service offering to the viral and gene therapy marketplace. The company's Life Science business has close to three decades of experience in cell and gene therapy, and its Carlsbad site has been involved in the gene therapy area since 1997, near the time that clinical trials for gene therapy began. In the interim, the company's Life Science business manufactured viral vectors for two cell and gene therapy products.

This expansion underscores the Life Science business' continued investment in viral and gene therapies from clinical to commercial scale and marks the second major investment at the Carlsbad facility in recent years. In 2016, the investments resulted in nearly doubling its former production capacity. The upgraded facility grew from 44,000 square feet to 65,000 square feet. Today, the Carlsbad site is home to 16 modular viral bulk manufacturing cleanroom suites with single-use equipment and two fill/finish suites for gene therapy, viral vaccine and immunotherapy products. The expansion will add 11 suites, bringing the total to 27, used in various steps of manufacturing.

In addition to contract development and manufacturing services for viral vectors, the company's Life Science business also provides seamless manufacturing and testing services at its pharma and biopharma testing sites globally.

Merck KGaA, Darmstadt, Germany, recognizes that cell and gene therapy has resulted in major advancements in medicine. The company supports these therapies under consideration of ethical and legal standards; it has established an independent, external [Bioethics Advisory Panel](#). This panel provides guidance on

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various topics, including gene editing and stem cells usage, in which its businesses are involved. The company has also defined a clear operational position taking into account scientific and societal issues.

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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 57,000 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 2019, Merck KGaA, Darmstadt, Germany, generated sales of €16.2 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.