

News Release

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Merck KGaA, Darmstadt, Germany, Brings Customers Closer to Gene Therapy Product Commercialization

- **Company's Carlsbad, U.S., manufacturing facility passes FDA and EMA inspections**
- **Underscores capabilities as commercial manufacturer of viral and gene therapy products**
- **Highlights position as leading contract manufacturing organization (CMO) for production of next-generation gene therapies**

Darmstadt, Germany, October 19, 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that its Carlsbad, California-based manufacturing facility for the production of BioReliance® viral and gene therapy products has completed both a U.S. Food & Drug Administration (FDA) Pre-License inspection and a European Medicines Agency (EMA) Marketing Authorization Application inspection.

“The successful FDA and EMA inspections of our Carlsbad manufacturing facility mark an important milestone for us and our customers who are manufacturing exciting new treatments for cancer and many other diseases,” said Udit Batra, Member of the Executive Board of Merck KGaA, Darmstadt, Germany, and CEO, Life Science. “As one of the first CMOs in the industry to complete pre-licensure inspections for this class of therapies, this achievement underscores our commitment to bring our customers one step closer to commercialization of novel therapies.”

These inspections will enable one of the key customers of Merck KGaA, Darmstadt, Germany, to launch its novel gene therapy in both the U.S. and in Europe, which is

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currently under review by both the FDA and EMA. The inspections were significant milestones in the approval process to obtain the licenses necessary to manufacture the gene therapy as a commercial product.

This key benchmark underscores the continued investment of Merck KGaA, Darmstadt, Germany, in viral and gene therapies from clinical to commercial scale. Merck KGaA, Darmstadt, Germany, has close to three decades of experience in gene therapy, and its Carlsbad site has been involved in the gene therapy area since 1997, near the time clinical trials for gene therapy began.

The Carlsbad facility provides contract development and manufacturing services that can contribute to a more efficient delivery of these lifesaving therapies to market. The business serves many leading developers of viral and gene therapy products globally.

The company's Carlsbad facility underwent a major expansion in 2016, and is now nearly double its former production capacity. The upgraded facility grew from 44,000 square feet to 65,000 square feet and now includes 16 modular viral bulk manufacturing cleanroom suites with single-use equipment and two fill/finish suites for gene therapy, viral vaccine and immunotherapy products.

Merck KGaA, Darmstadt, Germany, also offers viral and gene therapy manufacturing capacity in Glasgow, Scotland, has cell-banking services in Rockville, Maryland, and offers BioReliance® biosafety testing globally for both clinical and commercial stage gene therapy products.

Gene therapy involves the delivery of genetic material into patient cells to produce a therapeutic effect such as correction 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.

Merck KGaA, Darmstadt, Germany, recognizes the potential benefits of conducting properly defined research with genome editing because of the breakthrough therapeutic potential. Therefore, research with genome editing is allowed with careful consideration of ethical and legal standards. The company has established

the Merck KGaA, Darmstadt Germany, Bioethics Advisory Panel to provide guidance for research in which Merck KGaA, Darmstadt, Germany, is involved, including research on or using genome editing.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries. Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the „Merck“ name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.