

News Release

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Merck KGaA, Darmstadt, Germany Drives Thought Leadership in Ethical Gene Editing

- Co-authored paper, "Ethical Considerations in the Manufacture, Sale and Distribution of Genome-Editing Technologies," accepted in leading bioethics journal
- Highlights importance of science-based bioethics in genome editing and novel processes to ensure products meet the highest standards

Darmstadt, Germany, June 12, 2018 – Merck KGaA, Darmstadt, Germany, a leading science and technology company and leader in genome editing, today announced that *The American Journal of Bioethics* has accepted a novel publication on ethical issues in genome editing to be printed in its July issue. A summary version has been published in *The American Journal of Bioethics'* blog.

"Publication of this work demonstrates that Merck KGaA, Darmstadt, Germany is a true ethical innovator," said Udit Batra, member of the Executive Board and CEO, Life Science business of Merck KGaA, Darmstadt, Germany. "The company established a Bioethics Advisory Panel — a diverse group of global biomedical experts — to provide guidance for research in which its businesses are involved, including research on or using genome editing. We take this work very seriously."

Co-authored by colleagues from the company's Bioethics Advisory Panel, a diverse group of global biomedical experts, and colleagues from the company's from <u>Life Science</u> and <u>Healthcare</u> businesses, the publication discusses the critical ethical issues involved with the practical processes of manufacture, sale and distribution of genome-editing technology products such as Clustered Regularly Interspaced Short Palindromic Repeat (CRISPR).





"Our paper will enrich international deliberations about ethical issues in gene editing to incorporate the critical perspectives and responsibilities of suppliers," said Jeremy Sugarman, the Harvey M. Meyerhoff professor of bioethics and medicine at the Johns Hopkins Berman Institute of Bioethics, and lead author of the publication. Sugarman is also a member of the Bioethics Advisory Panel.

"As a company that is leading the way in genome-editing innovation, Merck KGaA Darmstadt, Germany recognizes a need to develop and implement science-based bioethics," said Steven Hildemann, global chief medical officer at the Healthcare business of Merck KGaA, Darmstadt Germany, and senior author of the publication. "This publication describes our novel approach to ensure our genome-editing products are developed and distributed adhering to the highest standards of rapidly evolving bioethical guidance."

The company's Bioethics Advisory Panel has defined a clear operational <u>position</u> taking into account scientific and societal issues to inform promising therapeutic approaches for use in research and applications.

A popular method of editing genes, CRISPR acts as genetic scissors which can be used to remove or replace an existing gene, switch a gene on or off or insert a new gene with unprecedented accuracy. The publication leverages MilliporeSigma's experience in developing and selling CRISPR genome-editing technology over the past 13 years.

The Life Science business of Merck KGaA, Darmstadt, Germany has secured patents in Australia, Canada, China, Europe, Israel, Singapore and South Korea covering foundational CRISPR technology. Its CRISPR patents are directed to chromosomal integration, or cutting of the sequence of eukaryotic cells and insertion of a synthetic exogenous DNA sequence to make a desired genomic change. Scientists can replace a disease-associated mutation with a beneficial or functional sequence — important for creating disease models and allowing new gene therapy solutions.

The company has made significant contributions to the genome-editing field. It was the first to offer custom biomolecules for genome editing globally (TargeTronTM RNA-guided group II introns and Compo Zr^{TM} zinc finger nucleases), driving adoption of



these techniques by researchers all over the world. MilliporeSigma was also the first to manufacture arrayed CRISPR libraries covering the entire human genome, accelerating cures for diseases by allowing scientists to explore more questions about root causes.

An online preview of the genome-editing bioethics publication in *The American Journal of Bioethics* can be found at:

http://www.bioethics.net/2018/05/ethical-considerations-in-the-manufacture-sale-and-distribution-of-genome-editing-technologies/

For more information on MiliporeSigma's work in the genome-editing field, visit https://www.emdgroup.com/en/stories/350-anniversary-its-all-in-the-genes.html and

http://ar.emdgroup.com/2017/magazine/new-ways-of-identifying-disease

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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. Almost 53,000 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 2017, Merck KGaA, Darmstadt, Germany, generated sales of € 15.3 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.