

News Release

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Merck KGaA, Darmstadt, Germany, Announces € 59 Million Antibody-Drug Conjugate Manufacturing Expansion

- **Creates one of the largest single-digit nanogram containment manufacturing facilities for high-potent active pharmaceutical ingredient (HPAPI) production**
- **Allows continuous flow manufacturing for antibody-drug conjugates (ADCs)**
- **Approximately 50 full-time jobs to be added**

Darmstadt, Germany, September 9, 2020– Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced a € 59 million expansion of its HPAPI and ADC manufacturing capabilities and capacity at its facility near Madison, Wisconsin, USA. This investment will allow large-scale manufacturing of increasingly potent compounds for therapies that have the potential to treat cancer. Completion is expected by mid-2022 and should add approximately 50 full-time jobs starting in 2021.

“ADCs have posted incredible growth over the last decade, and regulatory agencies’ approvals in recent years demonstrate their promise as a targeted therapy,” said Andrew Bulpin, Head of Process Solutions at the company’s Life Science business sector. “With more than 35 years of experience in this space, we have been a frontrunner in the development and manufacturing of biologics, conjugation processes and small molecules. This investment underscores our commitment to working with innovators to bring new treatments to patients quickly and more efficiently.”

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The company's new 6,500-square-meter commercial building will be one of the largest dedicated HPAPI manufacturing facilities specifically designed to handle single-digit nanogram occupational exposure limit materials. The project is an addition to the company's Madison campus, which was the first commercial ADC facility in North America designed to handle highly active materials. The new building will join the company's established campus in St. Louis, Missouri, USA, which specializes in ADC bio-conjugation, active pharmaceutical ingredients, excipient and adjuvants manufacturing.

ADCs are an emerging class of medicines designed for high-specificity targeting and destruction of cancer cells, while preserving healthy cells. There are now only nine ADCs approved globally. However, the ADC industry is delivering strong growth and is expected to reach € 13 billion by 2030¹.

While ADCs can provide many benefits compared with other therapeutic options, they also present a unique set of challenges. Their development is complex, necessitating stringent containment infrastructure, and their structural exceptionality requires expertise in a number of different technologies for small and large molecules, as well as analytical capabilities. Due to these challenges, more than 70 percent of ADC projects are outsourced to contract development and manufacturing organizations².

With more than 35 years of experience in the development and manufacturing of small molecules, biologics and ADC technologies, the Life Science business of Merck KGaA, Darmstadt, Germany, offers extensive experience in both clinical and commercial manufacturing. The company's comprehensive service portfolio combines the steps of drug development and production — from pre-clinical to commercial — from a single source. This consolidation helps reduce risk and streamlines the process of getting therapies to patients faster.

¹ "Antibody-Drug Conjugates Market to Be Worth \$15bn by 2030." European Pharmaceutical Review, 30 Aug. 2019, www.europeanpharmaceuticalreview.com/news/98037/antibody-drug-conjugates-market-15bn-2030/.

² Roots Analysis Private Ltd. ADC Contract Manufacturing Market, 2015-2025. August 2015, www.adc.expert/2mNns33

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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.