



News Release

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June 23, 2022

MilliporeSigma Opens US\$ 65 Million CDMO Facility to Address Demand for Critical Cancer Therapies

- **Expansion doubles production of the most highly potent active pharmaceutical ingredients (HPAPIs)**
- **MilliporeSigma now one of industry's largest manufacturers of these components globally**
- **Builds on company's 30 years' CDMO experience with multi-step, complex, and highly potent compounds**

Burlington, Massachusetts, June 23, 2022 – MilliporeSigma, the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany, a leading science and technology company, has doubled its high-potent active pharmaceutical ingredients (HPAPI) production capacity with the expansion of its facility in Verona, near Madison, Wisconsin, USA. This new US\$65 million, 70,000 square foot facility, officially opened today, brings 50 new jobs to the area.

"There is an increasing demand for HPAPIs due to their effectiveness against cancer at lower doses and the trend towards more targeted therapeutics. Lower-doses of these therapies reduce the negative side effects for patients who are taking on this critical fight," said Dirk Lange, Head of Life Science Services, Life Science business sector of Merck KGaA, Darmstadt, Germany. "Increasing capacity at our state-of-the-art facility in Verona, Wisconsin will allow us to meet the need for these key cancer treatment components."





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Cancer is the second leading cause of death worldwide¹. HPAPIs are a critical element of targeted therapies due to their extremely effective cell-killing abilities at low doses, resulting in reduced side effects for patients. They are used in novel cancer therapies, including antibody drug conjugates (ADCs), which are changing the landscape of cancer treatments.

MilliporeSigma has been developing multi-step, complex, and highly potent compounds for more than 30 years and continues to be an industry leader in the development and custom manufacture of these components. HPAPIs require specialized handling and manufacturing facilities that protect the safety of employees and their environment. Many potential life-saving treatments never make it to market in part due to the specialized handling requirements. MilliporeSigma's Verona, Wisconsin site was the second facility in the world to be SafeBridge[®]-certified and the company continues to meet these rigorous safety and containment requirements necessary to this day. In fact, this expansion positions MilliporeSigma as one of the largest single-digit nanogram occupational exposure limit (OEL) CDMO providers in the world. HPAPIs are measured with the most potent registering less than 10 nanograms per cubic meter. Single-digit nanogram HPAPIs require highly specialized handling, which is reflected by the OEL designation.

In addition to HPAPI production, MilliporeSigma also has extensive experience developing and manufacturing ADCs. Being the first CDMO to manufacture commercially approved ADC drugs in North America, the company recently launched new technologies to advance ADC therapies. Its unique ChetoSensor[™] technology gives new promise to ADCs by alleviating solubility challenges, and MilliporeSigma's new DOLCORE[™] platform significantly reduces development and manufacturing time required, increasing speed-to-market by up to a year, ultimately getting needed therapies to patients quicker.

¹ "Global Cancer Facts & Figures 4th Edition,
<https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/global-cancer-facts-and-figures/global-cancer-facts-and-figures-4th-edition.pdf>



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With more than 30 years of CDMO experience in the development and manufacturing of HPAPIs, linkers and mAbs, MilliporeSigma offers significant expertise in both clinical and commercial manufacturing. The company also has extensive CDMO experience in viral vector, lipids, LNP and mRNA manufacturing—from pre-clinical to commercial — helping to streamline steps of drug development and production with a single, highly experienced partner. Additionally, BioReliance® contract testing services are integrated into the overall Services offering to further streamline the development path.

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About the Life Science business of Merck KGaA, Darmstadt, Germany

The Life Science business of Merck KGaA, Darmstadt, Germany, which operates as MilliporeSigma in the U.S. and Canada, has more than 26,000 employees and 55 manufacturing and testing sites worldwide, with a portfolio of more than 300,000 products focused on scientific discovery, biomanufacturing and testing services. Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and electronics.

Around 60,000 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 2021, Merck KGaA, Darmstadt, Germany generated sales of € 19.7 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 Electronics. Since its founding in 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. For more information about Merck KGaA, Darmstadt, Germany, visit www.emdgroup.com.