

## News Release

Your Contact

**Media Relations**

[gangolf.schrimpf@emdgroup.com](mailto:gangolf.schrimpf@emdgroup.com)

Phone: +49 6151 72-9591

**Investor Relations**

[investor.relations@emdgroup.com](mailto:investor.relations@emdgroup.com)

Phone: +49 6151 72-3321

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## **Merck KGaA, Darmstadt, Germany, Accelerates Scale Up of Lipids to Meet Covid-19 Demand**

- **Introduces new synthetic cholesterol product nine months ahead of schedule**
- **Offers high purity, scalability, and consistent quality**
- **One of a few companies that produces lipids in quantities needed to meet demand for mRNA therapeutics, including Pfizer-BioNTech Covid-19 Vaccine**

Darmstadt, Germany, May 26, 2021– To meet the high demand for lipids, a key component of mRNA-based vaccines and therapeutics, Merck KGaA, Darmstadt, Germany, a leading science and technology company, has launched a new, high-purity synthetic cholesterol product, nine months ahead of schedule.

“Tapping into two decades’ experience of developing and manufacturing high-quality lipids, we designed a proprietary process to bring our new SAFC® synthetic cholesterol product to market nearly a year early,” said Andrew Bulpin, head of Process Solutions, Life Science, at Merck KGaA, Darmstadt, Germany. “With the introduction of our new SAFC® synthetic cholesterol product, we have increased our capacity by 50 times, helping biomanufacturers bring lifesaving therapies to patients faster.”

Merck KGaA, Darmstadt, Germany, manufactures lipids in Schaffhausen, Switzerland; Darmstadt, Germany; and St. Louis, Missouri, USA. While there are



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animal-derived and synthetic versions of cholesterol available on the market, the synthetic cholesterol product from Merck KGaA, Darmstadt, Germany, offers high purity, scalability, and consistent quality.

This neutral lipid, used in commercially marketed products, is more than 99 percent pure; offers high batch-to-batch consistency and is scalable under commercial GMP. Merck KGaA, Darmstadt, Germany, is one of a few companies in the world able to produce the quantities needed for lipid nanoparticle manufacturing and meet the quality requirements for mRNA therapeutics.

The launch of this new product follows the company's acquisition of AmpTec, a Hamburg, Germany, based mRNA contract development and manufacturing organization. By combining AmpTec's PCR-based mRNA technology with the extensive expertise of Merck KGaA, Darmstadt, Germany, in lipids manufacturing, Merck KGaA, Darmstadt, Germany, can provide a truly integrated offering across the mRNA value chain. Merck KGaA, Darmstadt, Germany, has more than 20 years of experience developing and manufacturing high-quality lipids, following GMP processes. The company provides regulatory support through all phases of clinical development and commercialization, as well as deep analytical expertise.

Merck KGaA, Darmstadt, Germany, is collaborating with more than 50 companies to support their efforts in the development and production of Covid-19 vaccines and treatments, providing custom lipids, as well as other critical raw materials, processing equipment and services used in mRNA drugs and vaccines manufacturing. In early February 2021, the company announced the extension of its strategic partnership with BioNTech to significantly accelerate the supply of urgently needed lipids and increase the quantities to be delivered toward the end of 2021. The lipids will be used for the production of the Pfizer-BioNTech Covid-19 vaccine.

The company recently announced the addition of a single-use assembly production unit at its Life Science Center in Molsheim, France. The company also recently announced expansion projects in Darmstadt, Germany; Cork, Ireland; Buchs, Switzerland; Carlsbad, California; Madison, Wisconsin; Jaffrey, New Hampshire; and Danvers, Massachusetts. At the latter site, Merck KGaA, Darmstadt, Germany, is

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working to double the local single-use production capacity by the end of 2021. These expansions are part of an ambitious, multi-year program to increase the industrial capacity and the company's capabilities to support growing global demand for lifesaving medications and to make significant contributions to public health.

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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 electronics. Around 58,000 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 2020, Merck KGaA, Darmstadt, Germany, generated sales of € 17.5 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.