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Merck KGaA, Darmstadt, Germany, and BioNTech Extend Strategic Partnership Through Accelerated Supply of Urgently Needed Lipids

Darmstadt, Germany, February 5, 2021 – Merck KGaA, Darmstadt, Germany, and BioNTech are further expanding their strategic partnership. Merck KGaA, Darmstadt, Germany, in close collaboration with BioNTech, will significantly accelerate the supply of urgently needed lipids and increase the amount of lipid delivery towards the end of 2021. The lipids will be used for the production of the Pfizer-BioNTech Covid-19 Vaccine (BNT162b2).

Lipids are critical to the drug delivery system of mRNA therapies to the body for a vaccine to be effective. Only very few companies in the world are currently able to produce custom lipids in significant quantities and according to the highest quality requirements needed for vaccine production.

"What unites BioNTech and Merck KGaA, Darmstadt, Germany, is our strong belief in mRNA technology and our trustful collaboration in vaccine development. We are convinced that now is the time to pull together to supply as much vaccine as possible to the world. Extraordinary times like these require bold steps, and we are ready to take these steps to tackle one of the biggest challenges of humanity", said Stefan Oschmann, Chairman of the Executive Board and CEO of Merck KGaA, Darmstadt, Germany.





With the outbreak of the pandemic, Merck KGaA, Darmstadt, Germany, and BioNTech had started to intensify their previously existing collaboration.

In the past weeks, Merck KGaA, Darmstadt, Germany, has been working hard to expand its already very high lipid production capacity. This required the further development of production technologies and the implementation of new, highly complex process steps. BioNTech and Merck KGaA, Darmstadt, Germany, are currently defining exact requirements and are aiming for a timely execution of their joint efforts.

Merck KGaA, Darmstadt, Germany, is a global leader in lipids. The company has extensive expertise in providing custom lipids and other critical components such as synthetic cholesterol for lipid nanoparticle formulations. Merck KGaA, Darmstadt, Germany, is active across multiple steps of the process flow and collaborates with many companies using lipid-based technologies to address Covid-19 vaccines and treatment.

Support of more than 50 vaccine projects worldwide

Since the outbreak of the pandemic, Merck KGaA, Darmstadt, Germany, has been intensely involved in the fight against the coronavirus. The Life Science business sector is supporting more than 50 vaccine projects worldwide with products and technologies. The company's role is comparable to that of a supplier in the automotive sector. Depending on the project, the company supports the research and development process, for which it offers raw materials and products such as proteases or antibodies. The company also offers a full spectrum of products used throughout the subsequent manufacturing processes for Covid-19 vaccines.

Because vaccine manufacturing is very complex and no standardized processes for innovative vaccines exist, Merck KGaA, Darmstadt, Germany, supports its customers in developing customized manufacturing platforms that enable industrial-scale production. Many of the company's products are used for this purpose, for example single-use assemblies, systems for biopharmaceutical production and consumables.



Integrated offering across the mRNA value chain

With the acquisition of AmpTec, announced in early January, Merck KGaA, Darmstadt, Germany, has further strengthened its capabilities and capacities for the development and production of mRNA. In particular, the combination of AmpTec's PCR-based mRNA technology with the company's extensive expertise in lipids manufacturing makes it possible to provide a truly integrated offering across the mRNA value chain.

In addition to vaccine development and production, Merck KGaA, Darmstadt, Germany, also supports more than 35 Covid-19 testing solutions and is collaborating with many clinical laboratories and diagnostics manufacturers. The company supplies critical raw materials across all key steps involved in diagnosing Covid-19 infections with PCR tests, such as oligonucleotide primers. In addition, it manufactures key products such as Hi-Flow membranes, for serologicals that enable testing for the presence of Covid-19 antibodies.

The Pfizer-BioNTech Covid-19 Vaccine (BNT162b2), which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer, and the marketing authorization holder is BioNTech in the United States, Europe, the United Kingdom, Canada, and other countries. It has been authorized for use by the health regulatory authorities of about 50 countries, including Switzerland and the European Union member states where it has been granted Conditional Marketing Authorization, and it has received authorizations for emergency use in e.g. the United Kingdom, the United States, and Canada. According to the data from the global Phase III clinical trial, the vaccine met all primary efficacy endpoints, demonstrating effectiveness of 95% in preventing Covid-19 in adults and 94% in adults over 65 years of age.



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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 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 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.