

New lipid facility at Evonik's site in Hanau to produce clinical and launch quantities of lipids for innovative medicines

- All types of custom lipids can be produced for clinical development and commercialization
- New cGMP lipid launch facility enhances current comprehensive lipid capabilities
- Further strengthens position as integrated solutions provider for mRNA and nucleic acid therapies

Essen, Germany. Evonik is building a new cGMP facility to manufacture lipids for clinical development and launch of innovative medicines. The new cGMP lipid launch facility is located in Hanau, Germany and will provide customers with smaller batch sizes of lipids as needed for clinical development. This cGMP expansion enhances the current gram-scale development lab and enables Evonik to meet the needs of partners at every stage of commercialization. With particle engineering and purification capabilities, including chromatography, the new facility can support customers with production of all types of custom and proprietary lipids, including PEGylated lipids, phospholipids, and ionizable cationic lipids. Start of operation is planned for the beginning of 2023.

The lipid launch facility will further expand Evonik's integrated portfolio of System Solutions for advanced drug delivery of mRNA and nucleic acid therapies including siRNA, oligonucleotides, and gene delivery. These are crucial for medicines of the future.

With the new lipid launch facility, Evonik continues its commitment to this important technology, offering end-to-end solutions for pharma and biotech companies from pharmaceutical formulation up to large-scale commercialization. In June this year, Evonik announced a triple-digit million-dollar joint investment with the U.S. Government to build a new lipid production facility at its site in Tippecanoe in Indiana, U.S. At the beginning of 2022, Evonik also increased production capacities for the plant-derived cholesterol PhytoChol® – a key lipid used in lipid nanoparticles – at its Hanau site in Germany. Evonik's laboratories in Vancouver

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have been working on preclinical development and clinical manufacturing for lipid-based, parenteral drug formulations, including LNPs and liposomes, for over three decades.

“With our new capability to produce kilogram quantities in Hanau, we are excited to offer our pharma customers more of the lipids they want in the amounts they require. We are confident this will contribute to the success of clinical studies and, ultimately, the approval of more new therapies,” says Thomas Riermeier, head of Evonik's Health Care business.

The types of lipids that can be produced at the kilogram scale will serve a broad range of mRNA and gene therapies such as infectious disease control, cancer immunotherapy, protein replacement and gene therapy. The lipid launch facility will now allow customers to obtain cGMP material consistent with larger scale production, enabling a seamless path for scale up. This consistency across different scales from development to commercial production allows customers to gain important information, for example, on impurities or toxicological properties that are otherwise difficult to test at laboratory scale.

“We continue to enhance our offering as a reliable partner by developing and producing custom and proprietary lipids for leading players to help them realize the potential of gene therapies. Our lipid launch facility now provides our customers with tailored solutions for higher efficiency in early development stages,” says Paul Spencer, head of Drug Delivery & Products at Evonik's Health Care business.

Lipids make up the building blocks of living cells and are critical for producing mRNA-based drugs. The mRNA is enclosed in a lipid nanoparticle (LNP) composed of specific lipids. This LNP protects the mRNA from degradation and delivers it safely into the cell, where it is released. LNPs are currently the most advanced drug delivery system and have gained worldwide acceptance in the fight against COVID-19 due to their versatility. During the coronavirus pandemic, Evonik made a crucial contribution by providing specialty lipids to the Pfizer/BioNTech COVID-19 vaccine COMIRNATY®.

As a partner to the pharmaceutical industry, Evonik has been a leader in advanced drug delivery for decades. It supports pharmaceutical companies worldwide with comprehensive services for developing and manufacturing complex parenteral and oral drug products. This includes pharmaceutical excipients such as lipids and custom lipids, formulation development and the manufacturing of clinical samples, as well as commercial drug products.

The Health Care business is part of the life sciences division Nutrition & Care, which aims to increase its share of System Solutions from 20 percent today to more than 50 percent by 2030. These are multi-component offerings across products, technologies and services that provide customers with end-to-end development and manufacturing services.

Company information

Evonik is one of the world leaders in specialty chemicals. The company is active in more than 100 countries around the world and generated sales of €15 billion and an operating profit (adjusted EBITDA) of €2.38 billion in 2021. Evonik goes far beyond chemistry to create innovative, profitable and sustainable solutions for customers. About 33,000 employees work together for a common purpose: We want to improve life today and tomorrow.

About Nutrition & Care

The focus of the business of the Nutrition & Care division is on health and quality of life. It develops differentiated solutions for active pharmaceutical ingredients, medical devices, nutrition for humans and animals, personal care, cosmetics, and household cleaning. In these resilient end markets, the division generated sales of €3.56 billion in 2021 with about 5,300 employees.

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