

PRESS RELEASE

Joint Press Release from WACKER and CordenPharma

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WACKER and CordenPharma Develop Solutions for Formulating Lipid Nanoparticles Expanding Their Portfolio for Advanced Medicines

Munich / Luxembourg, December 14, 2021 – WACKER and CordenPharma have signed a development partnership in the field of Lipid Nanoparticle formulation. The two companies announced today that they plan to jointly develop know-how and processes for the manufacturing of Lipid Nanoparticles (LNPs) to be used to meet the growing market demand. LNPs are drug delivery systems for nucleic acid therapeutics consisting of special fats, which ensure that actives can safely enter the body in order to exert their biological effect. The protective capsules are an essential component of advanced medicines such as mRNA-based drugs, protein replacement therapeutics, and antibody therapeutics.

Within the partnership, both companies will first jointly build up research and development capacities for developing solutions in the field of LNP formulation at their respective manufacturing sites – Wacker Biotech in Amsterdam and CordenPharma in Caponago, Italy. The aim is to offer a broad spectrum of LNP formulations, which the companies plan to produce as contract manufacturers according to Good Manufacturing Practice (GMP) guidelines.

CordenPharma's global network of API (Active Pharmaceutical Ingredients) manufacturing facilities will contribute its many years of expertise in the area of lipid excipient manufacturing. The CordenPharma Caponago facility, a leading manufacturer of injectables with a track record of more than 20 years in both terminal

and aseptic fill & finish, will supply the LNP formulation development, manufacturing and fill & finish. As a manufacturer of active ingredients, WACKER, at its Amsterdam biotech site, produces messenger ribonucleic acid (mRNA) actives, which are often used as vaccines or therapeutic agents in LNP formulations. In addition, the company will also offer expertise in the production of plasmid DNA (pDNA), an essential intermediate for mRNA.

Lipid Nanoparticles consist of special fats (lipids), which encapsulate the active and ensure that it is safely transported into the body cells, for example by protecting peptides and therapeutic substances. First and foremost, though, they are an indispensable building block in the formulation of active ingredients based on mRNA. While demand for LNP has taken off in recent months with the development of mRNA-based vaccines against COVID-19, the broader field of mRNA-based actives is also projected to undergo dynamic growth. About 250 candidate actives are currently under development worldwide, some in the field of vaccines and others for therapeutics.

WACKER and CordenPharma already cover almost the entire manufacturing chain for mRNA – from lipid and pDNA manufacture, production of the mRNA active, through to formulation and drug product filling services. Their combined extensive expertise in the field of LNP formulation rounds out the portfolio. In the future, customers will benefit from receiving an entire mRNA toolkit from one source.

At its facilities in Switzerland, France, and Colorado in the USA, CordenPharma already manufactures a range of lipids, which are typically used for formulating LNPs for various synthetic mRNA-based

actives. “The manufacturing of Lipid Nanoparticles for mRNA formulation is a complex process requiring specific lipids. We are the experts in the development, scale-up and industrial production of these lipids covering a broad portfolio. We are excited to partner with WACKER to expand our service offerings, ultimately providing end-to-end solutions for ribonucleic acids, including fill and finish,” says Dr. Michael Quirnbach, President & CEO at CordenPharma.

While CordenPharma has long-term expertise in the field of lipid manufacturing and aseptic fill & finish, WACKER contributes its experience in actives manufacturing in general, and mRNA production in particular. Its biotech site in Amsterdam has been producing and filling vaccines for clinical development and commercial supply for 20 years. The site has seen investment over the past year to build up the expertise it needs to manufacture mRNA-based vaccines, too. The infrastructure necessary to enter LNP production is already available at the site. “I’m delighted that Wacker Biotech and CordenPharma are working on joint solutions for LNP formulations in research, development and production. As an experienced, highly proficient GMP contract manufacturer, this complements our service portfolio for our customers in the field of mRNA,” says Dr. Guido Seidel, who is responsible for the biopharmaceuticals business at WACKER. The Munich-based WACKER Group concentrates its biopharmaceuticals activities within Wacker Biotech.

About CordenPharma

CordenPharma, the global pharmaceutical service & manufacturing platform of International Chemical Investors Group (ICIG), is a full-

service partner in the Contract Development & Manufacturing (CDMO) of APIs, Excipients, Drug Products, and associated Packaging Services. Through a growing network of cGMP facilities across Europe and the US organized under five Technology Platforms – Lipids & Carbohydrates, Peptides, Injectables, Highly Potent & Oncology, and Small Molecules – CordenPharma experts translate complex processes and projects at any stage of development into high-value products. For more information, visit: cordenpharma.com

About Wacker Biotech

Wacker Biotech GmbH, Wacker Biotech B.V. and Wacker Biotech US Inc. are full-service contract manufacturers of therapeutic proteins, live microbial products (LMPs), vaccines based on microbial systems, and of plasmid DNA. Wacker Biotech's portfolio extends from strain/process development and analytical testing through to production for clinical and commercial applications. Wacker Biotech maintains three GMP-compliant (Good Manufacturing Practice), FDA- and EMA-certified production plants at its Jena and Halle sites in Germany and in Amsterdam in the Netherlands. The company's most recent acquisition is its San Diego site (Wacker Biotech US Inc.), added in February 2021. Wacker Biotech GmbH, Wacker Biotech B.V. and Wacker Biotech US Inc. are wholly-owned subsidiaries of the Munich-based WACKER Group. For more information, visit: wacker.com/biologics

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