



WACKER & CordenPharma Enter Pandemic Readiness on 1 June 2024 After Successful Expansion & Qualification

- Consortium formed between WACKER & CordenPharma has officially entered the pandemic readiness state as of 1 June 2024 to produce 80 million vaccine doses within a short time, if needed.
- Following a successful expansion and qualification phase, the companies are now in a standby readiness phase for at least five years.
- Should the need arise, the German government will contact the developer of the specific mRNA vaccine required and WACKER & CordenPharma will then jointly produce this mRNA vaccine in line with the highest pharmaceutical quality standards.

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WACKER and CordenPharma are pleased to announce their joint consortium has officially entered the pandemic readiness state as of 1 June 2024. Following a successful expansion and qualification phase, the companies are now in stand-by phase for at least five years.

Given the initial vaccine shortage during the coronavirus pandemic, the German government made the decision to strategically secure the production and supply of vaccines for the future, and as a result, companies were able to apply for pandemic-preparedness contracts with the German government. As joint bidders for the production readiness of mRNA-based vaccines, WACKER and CordenPharma were among those companies awarded a contract.

In the event of a new pandemic, WACKER and CordenPharma have taken the necessary steps to produce 80 million vaccine doses a year, within an extremely short time. The two companies will receive a fee to keep their production capacity and expertise available in a stand-by phase for at least five years. Should the need arise, the German government will contact the developer of the specific mRNA vaccine that is required. WACKER and CordenPharma will then jointly produce this mRNA vaccine in line with the highest pharmaceutical quality standards, with most of the production steps taking place in Germany, and every production step occurring within the European Union.

In its site in Halle (Germany), WACKER will produce plasmid DNA (pDNA), which is an essential starting material for the manufacture of mRNA. The mRNA active based on pDNA will also be produced there, along with the formulation using Lipid NanoParticles (LNPs) of the mRNA active. In preparation, WACKER therefore expanded its site over the last two years, culminating in the <u>recent announcement of their new mRNA Competence Center in Halle, Germany</u>.

As part of the consortium, CordenPharma is ready to manufacture custom and standard lipids in their Frankfurt (DE) and Chenôve (FR) sites, as well as provide aseptic fill & finish and packaging of the chosen mRNA-based vaccine at their Caponago (IT) facility.

During the two-year qualification phase, CordenPharma successfully invested in multiple expansions, including new lipid purification capacity and capabilities utilizing Supercritical Fluid Chromatography (SFC), and new compounding and freezing equipment. For pandemic readiness, WACKER and CordenPharma have furthermore strengthened their production security and supplier network, as part of a complex pandemic readiness strategy across the EU sites involved.

"We have expanded our Halle site into a Competence Center for mRNA production," said WACKER CEO Dr. Christian Hartel. "WACKER has invested over 100 million Euros in this expansion and created over 100 highly qualified jobs. Our expertise in making mRNA and LNPs will contribute to the fight against future pandemics. Together with CordenPharma, we are proud to serve the German government in its pandemic preparedness plans."

Dr. Michael Quirmbach, CEO of CordenPharma Group, commented: "Obtaining the official confirmation of pandemic readiness by the German government is a major milestone for CordenPharma. I am extremely proud of our teams across the CordenPharma sites involved in establishing and delivering our pandemic readiness plan on schedule. We are now ready, together with our partner WACKER, to manufacture end-to-end mRNA-based vaccines for the German government and other customers."



[Photo by CordenPharma] – Aseptic vial filling line in CordenPharma Caponago, Italy.



[Photo by WACKER] – Production takes place behind glass in cleanroom conditions at WACKER's mRNA Competence Center in Halle, Germany.

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), plasmid DNA (pDNA), messenger ribonucleic acid (mRNA) and vaccines based on microbial systems. WACKER Biotech's portfolio extends from strain/process development and analytical testing through to production for clinical and commercial applications. WACKER Biotech operates three GMP-compliant, FDA- and EMA-certified production plants at its Jena and Halle sites in Germany and in Amsterdam in the Netherlands. In addition, WACKER Biotech has had a plant in San Diego (WACKER Biotech US Inc.) since February 2021. WACKER Biotech GmbH, WACKER Biotech B.V. and WACKER Biotech US Inc. are wholly-owned subsidiaries of WACKER Chemie AG.

www.wacker.com/biologics

About CordenPharma

CordenPharma is a CDMO partner supporting biotech and pharma innovators of complex modalities in the advancement of their drug development lifecycle. Harnessing the collective expertise of the teams across its globally integrated facility network, CordenPharma provides bespoke outsourcing services spanning the complete supply chain, from early clinical-phase development to commercialization.

With scientific expertise and partnership at its core, CordenPharma provides customers high-value, end-to-end services with a strategic focus on Peptides, Oligonucleotides, customized Lipid Excipients, Lipid NanoParticles (LNPs), sterile Injectables, and the extensive supply of Small Molecules (both Highly Potent and Regular Potency).

The CordenPharma Group is comprised of 11 facilities across Europe and North America. In the 2023 financial year, the organization generated sales of 880 million Euros and had over 3,000 employees.

Please visit cordenpharma.com for more information.

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