CordenPharma Expands Early Clinical Peptide Manufacturing to Launch IND-Targeted Peptide API to Injectable Drug Product Integrated Offer

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After an initial expansion of the CordenPharma Frankfurt site for non-GMP manufacturing in 2020, and because of sustained success and exemplary performance delivered by their expert team, CordenPharma is pleased to announce the commissioning of new GMP capacities at Frankfurt to manufacture early clinical phase peptide APIs for pharma and biotech customers. The investment, which is still being finalized, will be fully operational in Q2 2024 and authorized by German authorities in H2 2024.

The Frankfurt site will add 1000 m^2 of manufacturing space, including two fully equipped lines comprised of a Solid Phase Peptide Synthesizer (SPPS), High Pressure Liquid Chromatography (HPLC), Liquid Phase (LP), isolation equipment and quality control laboratories including In Process Control (IPC), starting material batch release, and GMP stabilities. The GMP manufacturing area is designed to produce peptide APIs from gram to kilogram range for clinical phase 1 and 2 requirements. As the project progresses along the customer lifecycle, the new state-of-the-art technologies will enable a smooth and seamless transfer to the late phase and commercial manufacturing site CordenPharma Colorado (Boulder, US).

Moreover, the GMP expansion supports the launch of an integrated service offering between CordenPharma Frankfurt (for Peptide Drug Substance) and CordenPharma Caponago (IT) (for Injectable Drug Products) to deliver fully customizable technical, manufacturing, and regulatory support that is specifically targeted to enable efficient IND / IMPD filings, with all the necessary materials needed to initiate customers' First In-Human (FIH) clinical trials.

Through this integrated peptide-injectable offer, customers will benefit from:

- One CDMO relationship with a single contract, including quality agreement & project management
- API route selection, salt & solubility studies, API characterization, reference standard qualification
- Formulation development, analytical method development & validation
- Stability studies for development, toxicology & GMP batches
- Technical writing for the IND / IMPD submission

The bespoke offer is tailored for each individual customer and will enable pharma and biotech innovators to move their complex modalities quickly to tox batch and FIH clinical trials, while actively managing business requirements and balancing timelines and budget, without losing track of important project milestones.

Dr. Stéphane Varray, CordenPharma's Global Peptide Platform Director, commented: 'With our new early clinical GMP peptide manufacturing investment in Frankfurt and the launch of seamlessly integrated peptide API to injectable Drug Product services, CordenPharma is uniquely positioned to deliver customized CMC support for biotech customers and facilitate their successful IND / IMPD submissions and start of FIH clinical trials. We believe the offer will bring added-value and increased efficiency to our customers, and ultimately enhance the well-being of their patients."

[Photo by CordenPharma] Freeze drying isolation of APIs in the containment area of CordenPharma Frankfurt (DE).

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 12 facilities across Europe and North America. In the 2023 financial year, the organization generated sales of 890 million Euros and had over 3,000 employees.

Please visit cordenpharma.com for more information.

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