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CordenPharma Increases xRNA-based Capabilities with a Strategic Investment in LNP Formulation Services at its Caponago Injectable Facility

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CordenPharma, a full-service Contract Development Manufacturing Organization (CDMO) of Active Pharmaceutical Ingredients (APIs), Excipients, Drug Products & Packaging services, has increased its xRNA capabilities at its sterile injectable facility in Caponago, Italy.

The company reports that it is investing over €10M in new Lipid Nanoparticle (LNP) formulation, development and production areas. The expansion will support customers to progress from pre-clinical and clinical development of xRNA-based therapeutics (mRNA, siRNA, saRNA, microRNA, & similar), enabling them to maximize and speed up the delivery of their innovative drug products into clinical stages and beyond.

The initial phase has now started with CordenPharma expanding its R&D laboratory with LNP formulation development and analytical characterization capabilities at its CordenPharma Caponago sterile injectable facility.

CordenPharma's capital investments will help introduce this advanced pharmaceutical manufacturing technology to Europe and support the creation of a highly resilient supply chain and robust next-generation operations. In addition to LNP formulation, the expansion will integrate the sourcing of lipids from within the CordenPharma network, combining them seamlessly into the targeted genetic payload.

CordenPharma's Caponago operations are set for expansion from late 2022 into early 2023 with the construction of a new hub for LNP formulation with cGMP manufacturing, where clinical batches at any stage, including small commercial drug products that adopt LNP technology, will be made. The build-out will create up to 15 high-level jobs, which CordenPharma plans to recruit and fill over the coming months.

Fabio Stevanon, Global Injectable Platform Director of CordenPharma, said: "Our planned investment into LNP formulation capabilities is a major step forward for CordenPharma. It will not only boost innovation in R&D, but also give us cutting-edge manufacturing for the benefit of our customers.

RNA-based therapies, including the more familiar mRNA products, are becoming more widely used, so the use of LNP is a particularly effective formulation approach for these products. CordenPharma is already recognised as a leading global source of synthetic lipids. As a result, this investment in LNP capability integrated into our fully-approved sterile Injectable site allows a "one-stop-shop" for our customers."

CordenPharma's LNP formulation technique utilizes two different LNP assembly technologies: Microfluidic and Jet-Impingement. Microfluidic technology controls the flow of two different solutions (water-based and lipid-based), then mixes them in a precise manner to deliver small, uniform particles capable of sterile formulation for proper introduction into the human body. The second technology that CordenPharma will be deploying is Jet-Impingement, via a modified T-Junction. This technology will be especially suited to accommodate larger-scale manufacturing.

This new LNP cGMP capability will be constructed alongside existing injectable formulation technologies, enabling CordenPharma to easily drive LNP-based drug formulations into liquid (vial or syringe) or lyophilized finished dosage forms.

CordenPharma Caponago (IT) LNP R&D Laboratory: TFF equipment for diafiltration and concentration of Lipid Nanoparticle formulations.

In March 2022, CordenPharma conducted its first positive tests of assembly and characterization of functional Lipid Nanoparticles by combining mRNA sourced from partner WACKER and Lipids internally sourced from CordenPharma sites (located in Switzerland and France) to produce a prototype formulation.

Along with its investment in LNP services, CordenPharma plans on expanding its drug product primary and secondary packaging capabilities at Caponago, adding highly automated, high-throughput filling and packaging lines to provide customers with new ways to dispense and deliver medications to patients. The additional capacity will focus on Pre-filled Syringes (PFS) and similar parenteral delivery technologies including unit-dose, and in the future, dose-injector devices.

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 – Peptides, Lipids & Carbohydrates, Injectables, Highly Potent & Oncology, and Small Molecules – CordenPharma experts translate complex processes and projects at any stage of development into high-value products.

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