



## CordenPharma Launches LNP Starter Kits to Mitigate Loss of High-value Payloads During the Gene Editing Journey to Market

28 February 2024 – Basel, Switzerland > CordenPharma International is pleased to announce the launch of new <u>Lipid NanoParticle (LNP) Starter Kits</u> for effective mRNA formulation in the development of mRNA-based therapeutics such as mRNA vaccines or gene therapies. The starter kits provide researchers and developers with the essential components needed to create and optimize their own LNPs for mRNA delivery.

Drawing from extensive experience spanning over three decades in supporting customers with lipid excipient CMC preparation, and more recently in scaling up key formulation elements of a commercialized COVID-19 vaccine, CordenPharma's scientific experts have mastered chemical processes and <u>purification steps</u> to ensure the highest quality lipids, with remarkable batch-to-batch reproducibility. To mitigate potentially negative outcomes and loss of valuable payload due to subpar lipid quality, the new LNP kits, which include four key lipids (ionizable lipids, helper lipids / sterols / PEGylated lipids), are meticulously curated using representative materials from commercial-scale sources. This approach eliminates the risk associated with changing lipid sources from the R&D phase to clinical phases.

CordenPharma lipid experts designed the LNP starter kits to facilitate easy formulation screening, enabling the generation of LNPs capable of providing efficient transfection in different cell types, including immortalized and/or primary cell cultures. The kits, which can be used for animal *in-vivo* applications including PK/PD studies and mRNA transfection efficacy POC/studies, <u>have been tested</u> with GFP-mRNA as cargo and successfully implemented for synthetic RNAs (such as siRNA) and DNA as well.

With easy-to-follow instructions included, users can fine tune the LNP formulation process to achieve the production of nanoparticles with the desired physicochemical characteristics, such as PDI ≤0.2 and a size range between 30-150 nm (depending on the specific LNP reaction conditions, lipid composition and cargo used).

The LNP Kits consist of both well-known and characterized formulations in a preclinical and clinical setting, (e.g. COVID-19 Vaccines) with various combinations available to benchmark / compare LNP formulations or create completely novel compositions that elevate formulations to the next level during screening phases.

Since transfection efficiency is now being recognized as one of the next challenges in LNP formulation, a tremendous diversity of structural cholesterol analogues exist as natural products (e.g., phytosterols that are plant-based sterols, which provide stability to the plant cell wall). In addition, endosomal sequestration of LNPs remains a formidable barrier to delivery. Recent structure-activity analysis of cholesterol analogues reveals that incorporation of  $\beta$ -sitosterol into LNPs enhances gene transfection. By leveraging years of extensive expertise gained in the process development of CordenPharma's Botanichol® (plant origin Cholesterol), they are proud to introduce this new highly pure sterol into some LNP Starter kits.

Dr. Matthieu Giraud, CordenPharma's Senior Director, Global Lipids & Carbohydrates Platform, commented, "CordenPharma is proud to introduce this new LNP Starter Kit concept, as it represents a great

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<sup>&</sup>lt;sup>1</sup> https://doi.org/10.1038/s41467-020-14527-2 | www.nature.com

synergy between our Lipid and LNP expertise that helps accelerate time to market and provide access to the most efficient compositions of the LNP-based drug development field for the delivery of RNA, DNA and gene therapy payloads across various important therapeutic indications, with an ultimately profound effect on saving the lives of patients."



CordenPharma LNP Starter Kits include four key lipids (ionizable lipids, helper lipids / sterols / PEGylated lipids).

Click or scan this QR code to place an order for CordenPharma's LNP Starter Kits.

Take advantage of our launch offer: all kit orders placed before 30 April 2024 will automatically receive a 25% discount.



## 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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