PRESS RELEASE

Peer-reviewed study demonstrates LEON's FR-JET® modular mixer enables stable high-concentration mRNA-LNPs with enhanced *in vivo* activity

Planegg/Munich (Germany), January 9th, 2026 – A new study published in *Pharmaceutics* (https://doi.org/10.3390/pharmaceutics18010050) shows that LEON's FR-JET® modular mixer addresses key manufacturing challenges by enabling the production of highly concentrated lipid nanoparticles (LNPs). The study demonstrates that LNP formulation at significantly higher lipid mixture concentrations, beyond those currently reported in the literature and industry sources, can improve biological function *in vivo*, streamline manufacturing, and improve storage stability.

Overcoming the bottleneck

"*There is growing recognition across the industry that LNP manufacturing challenges are not solely scientific, but are also largely operational in nature*," said Dr. Blerina Shkodra, lead author of the study. "*Using LEON's FR-JET® technology, we show that LNPs can be formulated at lipid mixture concentrations above 50 mg/mL, not only retaining product quality but also enhancing potency in vivo. These findings indicate a practical approach to simplified manufacturing and increased throughput, enabling drug innovators to bring life-saving mRNA therapies to patients faster and more efficiently*."

Traditional microfluidic mixers are frequently limited by clogging, poor robustness, and scalability barriers, while conventional T-mixers can exhibit inconsistent reproducibility often associated with scaling-out strategies that can complicate manufacturing. In contrast, LEON's FR-JET® modular mixer delivers a robust mixing, unlocking process intensification while supporting a predictable and direct scale-up.

Why formulation at significantly higher lipid mixture concentrations matters for LNP developers:

Manufacturability – process intensification: Manufacturing at higher starting material concentrations can shorten, or even eliminate, the initial rate-limiting ultrafiltration step in tangential flow filtration (TFF), reducing overall downstream process time and buffer consumption during diafiltration.

Product Performance – potency and dosing: Cryogenic transmission electron microscopy (Cryo-TEM) revealed more uniform, solid-core particles. Increased lipid and RNA concentrations can enhance *in vivo* potency, which may translate into improved tolerability and more efficient dosing strategies.

Product Quality – morphology and stability: Higher solid-core fractions indicate more uniform particle morphologies, alongside demonstrated colloidal stability for 3 to 6 months in two different buffer systems.

CMC Scalability – development to manufacturing: This approach supports smoother translation from formulation development to manufacturing scale, enabling more robust processes and easier technology transfer.

"*This peer-reviewed study validates the science behind the FR-JET® technology and confirms that our commercially available manufacturing systems are making a big difference,*" said Dr. Wolfgang Hofmann, CEO of LEON. "*It marks the beginning of a new phase for LNP manufacturing, and it paves the way for what LEON has prepared to deliver in 2026.*"

ABOUT LEON (leon-nanodrugs GmbH)

Based in Planegg/Munich, leon-nanodrugs GmbH is a Pharmatech company specializing in the development and commercialization of equipment for the encapsulation of genetic material and other pharmaceutical active substances into nanoparticles, such as lipid nanoparticles (LNPs). The company leverages its proprietary FR-JET® technology to build innovative solutions. Its equipment portfolio includes NANOscreen® for formulation screening, NANOlab® for process development, as well as NANOme® and NANOus® for GMP manufacture. These systems are suitable for both individualized scales and commercial production, and the company further supports its clients by offering formulation and process development services. LEON's platform aims to empower pharmaceutical companies, small biotech, research institutes, and CDMOs to capitalize on advancements in advanced therapies.

For further information, please visit https://leon-nanodrugs.com/ and follow us on LinkedIn.

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