

PRESS RELEASE

Harro Höfliger and LEON collaborate to bring the innovative NANOus LNP-encapsulation device to market for rapid, large-scale prophylactic vaccine manufacturing

- LEON and Harro Höfliger to build and commercialize LEON's NANOus, a novel aseptic manufacturing device to facilitate commercial production of LNP-encapsulated genetic materials and other APIs
- By enabling easy scale-up, PAT and GMP-compliance, NANOus targets unmet needs of pharmaceutical and biotech industries and CDMOs
- NANOus is the first product based on LEON's proprietary technology platform NANOnow
- Companies to attend CPHI in Frankfurt (Nov. 1-3, 2022)

October 26, 2022 – Allmersbach im Tal and Munich – The mechanical engineering and process specialist Harro Höfliger, and leon-nanodrugs GmbH ("LEON"), a disrupting enabler of nanotechnology for the pharmaceutical industry, today announce their collaboration on a manufacturing device to encapsulate mRNAs or active pharmaceutical ingredients (APIs) into lipid nanoparticles (LNPs). NANOus is a flexible small-to-high-volume manufacturing device designed for aseptic GMP-compliant nanoencapsulation of APIs, based on LEON's proprietary NANOnow technology.

The two companies are in the process of assembling the market-ready device, which will enable rapid and cost-efficient, seamless scale-up for production of LNP-encapsulated therapeutics. NANOus can enable continuous manufacturing of several million vaccine doses per day. The collaboration builds on Harro Höfliger's longstanding experience and engineering capabilities in order to meet the needs of the manufacturing pharmaceutical sector, while LEON provides access to its core technology platform NANOnow. The two companies will draw out the potential of LEON's proprietary jet-impinging reactor by implementing it into other devices and allowing commercial manufacturing of LNP-based therapeutics on a large scale, thus making LNP-based drugs more economically feasible for healthcare systems.

In this joint undertaking, the two companies will realize a state-of-the-art product, NANOus: While the LEON reactor itself allows for seamless scale-up from small to large volumes, high-flowrates without impacting product quality, and product concentrations several times higher than currently available devices, the NANOus device is built for commercial scale manufacturing. It will incorporate process analytical technology (PAT) to enable real-time product release. Staying true to LEON's maxim "One process, one reactor", scale-up takes place without any exchange of device equipment and therefore much faster.

"Harro Höfliger has taken a significant step into the aseptic manufacturing space already, not least on the back of our new baXeptic platform, thus demonstrating our ability to constantly advance our competencies – following our motto 'From Lab to Production'," said Thomas Weller, CEO of Harro Höfliger. "We're looking forward to expanding our footprint in the area of nanotechnology, as we are introducing innovative technical solutions together with LEON, through the efforts of the research and product development by our Pharma Services department."

Andrea Cusack, CEO of leon-nanodrugs, commented: "Harro Höfliger has an extensive track-record of successfully bringing new pharmaceutical production processes from lab-scale to commercial production. This makes Harro Höfliger the ideal partner for LEON as we seek to bring our technology to the

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biopharmaceutical industry. While the field of nanomedicine has really come to the forefront, we are aiming at unparalleled solutions to manufacturing those medicines in a very efficient and effective way. Our technology will allow much broader accessibility of mRNA vaccines, therapeutically enhanced biologics or small molecules, adding much needed targeted treatment options for all patients and their caregivers.”

LEON will be exhibiting at **CPHI 2022** in Frankfurt, Germany (November 1 to 3, 2022), presenting their NANOnow technology platform at Harro Höfliger's **booth 60C10** in Hall 6.

ABOUT HARRO HÖFLIGER

Harro Höfliger specializes in customer-oriented process and production solutions for pharmaceutical and medical applications as well as market-oriented consumer products. Among their core competencies are customized dosing and inhalation technology, solutions for product assembly and the processing of web materials. The company also offers extensive services regarding process development and the entire product life cycle.

Since being founded in 1975, the company with headquarters in Allmersbach im Tal (Germany) has been expanding continuously. In 2021, about 1,600 employees generated a turnover of around 300 million euros; the export rate is over 80 percent. For further information, please visit <https://www.hoeffliger.com> and follow us on [LinkedIn](#).

ABOUT LEON-NANODRUGS

leon-nanodrugs' ("LEON") aim is to create a new norm for the production of nanoparticle-based therapeutics by establishing their technology for seamless scale-up and high-performance output. The Munich-based private company was founded in 2011 and since then has successfully pursued its mission of enabling the biotechnology and pharmaceutical industry, as well as Contract Development and Manufacturing Organizations (CDMOs), with a disruptive manufacturing technology to encapsulate mRNAs or active pharmaceutical ingredients (APIs) into lipid nanoparticles (LNPs). The increase in efficiency and speed will broaden access to mRNA vaccines, therapeutically enhanced biologics or small molecules, and improve economic feasibility for the benefit of patients and healthcare systems. LEON's intellectual property is broadly protected with international coverage through 2041.

For further information, please visit <https://leon-nanodrugs.com/> and follow us on [LinkedIn](#) and [Twitter](#).

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