FDX Fluid Dynamix GmbH

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FDX Fluid Dynamix and Fraunhofer IPK to Collaborate with Lonza on Novel Nanoparticle Formulation Technology Platform FDmiX

Berlin (ots) -

- The collaboration aims to enable reliable and rapid scale-up to cGMP manufacturing for encapsulating nucleic acid products.
- This acceleration and the improved critical quality attributes (CQAs) of the final product allow for faster and more predictable development of nucleic acid-based products.

FDX Fluid Dynamix (FDX) and Fraunhofer Institute for Production Systems and Design Technology IPK today announced a collaboration with Lonza to accelerate the development of messenger RNA (mRNA) based therapies. FDX and Fraunhofer IPK jointly developed the FDmiX platform, a new generation of mixing devices for formulating nucleic acids (e.g., mRNA) in nanoparticle-based drug delivery systems (e.g., lipid nanoparticles).

The collaboration aims to commercialize this novel nanoparticle formulation technology for a predictable scale-up from research to commercial manufacturing scales.

Nucleic acid-based products, especially mRNA therapeutics, are an emerging class of biotherapeutics that offer new and unique opportunities for the prevention and treatment of various infectious diseases, cancers, autoimmune and genetic disorders.

mRNA products can be manufactured in short timelines, as recently demonstrated for COVID-19 vaccines. Since different formulation systems are needed for different scales, scaling up from pre-clinical development to commercial scales represents a major challenge. The FDmiX platform has the potential to provide a seamless scale-up from research to cGMP-grade nanoparticles with favorable CQAs.

FDmiX, which was developed by FDX Fluid Dynamix and Fraunhofer IPK, utilizes a unique oscillating flow that enables 6-8 times faster and more reliable mixing. This results in improved CQAs and higher yields thanks to consistent nanoparticle size and fewer filtration losses.

As part of the collaboration, Lonza has obtained a license for the IP-protected FDmiX encapsulation technology for all development scales and cGMP commercial manufacturing.

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Torsten Schmidt, Head of mRNA Business Unit, Lonza, commented: "This collaboration with FDX and Fraunhofer IPK allows us to offer a unique technology as part of our Lonza platform for the production of mRNA products from pre-clinical to commercial

scales."

Bernhard Bobusch, Chief Executive Officer, FDX Fluid Dynamix, adds: "We are excited to go the next step with the FDmiX platform with Lonza as a strong and enabling partner of this technology. As a company focused on optimizing flow processes in several markets, FDmiX is a great example of a technology where several professions have to come together to create the next great innovation. With Lonza and Fraunhofer IPK, we are happy to have the right partners for this technology."

Christoph Hein, Head of Business Unit High- and Ultraprecision Technologies, Fraunhofer IPK, adds: "The FDmiX platform is an excellent example of how applied research and entrepreneurial pioneering spirit can work together to create a solution that ultimately provides a benefit to each individual patient. For Fraunhofer IPK as an established R&D partner for industrial companies, the technology demonstrates the relevance of our research and shows the considerable impact it has on developing advanced solutions."

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Medieninhalte

Open mixing device FDmiX M-D with visible flow path. / More information via ots and www.presseportal.de/en/nr/173779 / The use of this image for editorial purposes is permitted and free of charge provided that all conditions of use are complied with. Publication must include image credits.

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