Shin Elsu 部 北海道大学

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<u>Shin-Etsu Chemical and Hokkaido University Develop Lipid Nanoparticle Production</u> <u>System Capable of Both Small-Batch, High-Mix Production and Mass Production</u>

Shin-Etsu Chemical Co., Ltd. (Head Office: Tokyo; President: Yasuhiko Saitoh; hereinafter, "Shin-Etsu Chemical") and Hokkaido University (Location: Hokkaido; President: Kiyohiro Houkin; hereinafter, "Hokkaido University") have developed system for the production of lipid nanoparticles (LNPs)*² that incorporates a microfluidic device*¹ as a component. Shin-Etsu Chemical will begin manufacturing this production system in April 2025, with Lilac pharma Inc. (Head Office: Hokkaido; President: Motoki Susa) serving as the distributor.

LNPs have been used in mRNA vaccines for COVID-19 and are expected to find broader applications in vaccines against various infectious diseases and cancer in the future.

In recent years, LNP production methods using microfluidic devices have attracted attention both in Japan and internationally. LNPs are created by rapidly mixing lipid and nucleic acid precursor solutions. Using a microfluidic device in the process enables more precise control of the LNP particle size than conventional manufacturing methods. However, there was a productivity issue with LNP production methods, as they could only produce small amounts of particles at a time.

By combining Hokkaido University's proprietary iLiNP[®] microfluidic device with Shin-Etsu Chemical's materials (primarily synthetic quartz) and processing technology, a microfluidic device has been developed that is suitable for use in mass production. Additionally, leveraging the system design expertise of our subsidiary Shin-Etsu Engineering, we have developed an LNP production system that mounts this microfluidic device and that complies with the GMP*³ requirements for pharmaceutical manufacturing.

A key advantage of LNP production system using microfluidic devices is its ability to adjust production volumes with a single system according to demand. With just one square meter of space, a single piece of system can manufacture different types of LNPs—from small-batch, diverse nanomedicine for personalized medicine^{*4} to mass-produced vaccines for infectious diseases. In the future, we aim to make this system into foundational infrastructure capable of manufacturing nanomedicine according to corporate needs during normal times and switching to vaccine production during pandemics.

Furthermore, the Shin-Etsu Chemical and Hokkaido University research group is developing an even more compact benchtop LNP production system for use in research and development, and aims to complete a prototype by the end of 2025. By providing a lineup of LNP production system appropriate for each stage, from R&D to mass production, we will enable a smooth transition to large-scale manufacturing.

Shin-Etsu Chemical will continue to leverage its technological capabilities and expertise to contribute to a sustainable society and industrial development.

*1 Microfluidic devices: Devices with small channels ranging from a few micrometers to several hundred micrometers in width.

*2 LNP: An abbreviation for Lipid Nanoparticle. LNPs are nano-sized particles primarily composed of lipids, typically ranging in diameter from 10 nm to 1,000 nm. They are also used in COVID-19 mRNA vaccines.

*3 GMP: Abbreviation for Good Manufacturing Practice (serves as standards for manufacturing and quality control of pharmaceuticals and quasi-drugs in Japan).

*4 Personalized medicine: Medical treatment that involves examining patients' genetic and other information to select treatment methods and medications tailored to each individual.

For inquiries about this matter, please contact:

Shin-Etsu Chemical Co., Ltd. Public Relations Dept. Tetsuya Koishikawa Tel: +81-3-6812-2340 Fax: +81-3-6812-2341 https://www.shinetsu.co.jp/en/inquiry/?d=shinetsu&t=shinetsu

Faculty of Engineering, Hokkaido University Associate Professor Masatoshi Maeki Tel: +81-11-706-6773 Fax: +81-11-706-6745 Email: m.maeki@eng.hokudai.ac.jp https://microfluidic.chips.jp/en/

Sohail Keegan Pinto (International Public Relations Specialist) Public Relations & Communications Division Office of Public Relations and Social Collaboration Hokkaido University Tel: +81-11-706-2186 Email: en-press@general.hokudai.ac.jp https://www.global.hokudai.ac.jp/