

News Release

## **Synplogen Signs MOU with Merck to Promote Process Development and Manufacturing of Viral Vectors for Gene Therapy**

**KOBE, Japan, December 9, 2022** - Synplogen Co., Ltd. (Head office: Nada-ku, Kobe; President and CEO: Kazuhiko Yamamoto; hereinafter referred to as "Synplogen"), a biotech startup spun out of Kobe University, has signed an MOU with Merck (hereinafter referred to as "Merck") to collaborate on the process development and GMP manufacturing of viral vectors for gene therapy.

Synplogen provides design, development, and analysis services for high-quality, cost-effective viral vectors for gene therapy (Gene Therapy Biofoundry Services), utilizing its proprietary ultra-long DNA synthesis technology. At its Kobe R&D Center, Synplogen can offer a wide range of services to meet customer needs, including DNA synthesis, plasmid DNA mass preparation, viral vector production, process development, characterization and quality testing, and support for technology transfer to GMP-compliant manufacturing facilities.

Merck is one of the world's leading science and technology companies providing viral vector manufacturing solutions covering process development, manufacturing and quality testing of adeno-associated virus (AAV) and lentivirus (LV) vectors, and is a leading CTDMO and technology development company.

“Synplogen has been providing customers with the technologies and services including DNA synthesis, cell, process and test method development necessary for gene therapy products, a market that has grown dramatically in recent years. Our collaboration with Merck will enable us to provide a full range of services from Chemistry, Manufacturing and Control (CMC) development to GMP manufacturing and potentially expand the business globally, by licensing our proprietary technologies to overseas companies,” said Kazuhiko Yamamoto, President and CEO of Synplogen Co., Ltd.

“With nearly 30 years’ experience in cell and gene therapy, we look forward to collaborating with Synplogen to further the development and manufacturing of viral vectors in Japan,” said Isao Hatano, Head of Process Solutions at Merck’s Life Science business sector in Japan. “Our work together will focus on developing the targeted template and manufacturing for viral vector in order to bring these life-changing therapies to more patients.”

Based on the MOU, Synplogen will receive technical consulting and support from Merck for the development of manufacturing processes and quality testing methods for gene therapeutic viral vectors from upstream to downstream processes, CTDMO services for investigational and commercial production of gene therapeutic viral vectors, as well as demonstrations and practical training through the M Lab™

Collaboration Center.

Merck's VirusExpress® 293 adeno-associated virus production platform is expected to shorten the time to investigational manufacturing for AAV vectors and accelerate the timeline of pipeline development for Synplogen's customers to move into clinical trials.

### **About Synplogen**

Synplogen Co., Ltd. is a synthetic biology startup company founded in 2017 and originated from Kobe University. Utilizing its proprietary DNA synthesis technologies "OGAB® method" and "Combi-OGAB™ method", the company is capable of synthesizing ultra-long and complex DNA and constructing DNA libraries with various combinations. We also provide one-stop solutions for the design, development, and analysis of high-quality, cost-effective viral vectors for gene therapy at our Kobe R&D Center, as a biofoundry specializing in gene therapy.

Head Office: 1-1 Rokkodai-cho Nada-ku, Kobe Japan  
Established: February 2017  
Representative: Kazuhiko Yamamoto, President and CEO  
Capital: 2,325.68 million yen (including capital reserve)  
Business: Custom DNA synthesis and biofoundry services for gene therapy  
URL: <https://www.synplogen.com/>

### **About Merck**

Merck, a leading science and technology company, operates across life science, healthcare and electronics. More than 60,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2021, Merck generated sales of € 19.7 billion in 66 countries.

### **About Merck Ltd.**

Merck Ltd. was founded in 1968 as the Japanese subsidiary of Merck. Merck Ltd. is engaged in products and services related to life sciences, including basic bioscience research, pharmaceutical manufacturing and drug discovery. Merck Ltd. is responsible for the life science business and Merck's administrative functions. For more information about Merck Ltd., please visit <https://www.merckgroup.com/jp-ja>.

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