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Sumitomo Dainippon Pharma Co., Ltd.
National Institutes of Biomedical Innovation, Health and Nutrition

Sumitomo Dainippon Pharma and National Institutes of Biomedical Innovation, Health and Nutrition Conclude Joint Research Agreement for Universal Influenza Vaccine

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) and National Institutes of Biomedical Innovation, Health and Nutrition (Headquarters: Ibaraki City, Japan; Director General: Yoshihiro Yoneda; hereafter NIBIOHN) announced today that they have concluded a joint research agreement, aiming at the practical application of a universal influenza vaccine that provides broader protection against most influenza.

Every year 3–5 million people suffer from severe conditions after seasonal influenza infections worldwide and 290,000–620,000 die from it (Lancet 2018). Conventional influenza vaccines lose potency due to virus antigen mutation and re-assortment; the need to be selected, manufactured, and vaccinated annually with vaccines tailored to prevalent strains estimated in each year makes it difficult for conventional vaccines to cope with new strains of influenza. Therefore, there has been a need for the development of a universal influenza vaccine that improves the breadth and durability of protection against seasonal influenza and potentially protects against pandemic strains.

In the joint research, using Sumitomo Dainippon Pharma's TLR7 adjuvant(DSP-0546LP)-containing vaccine formulations, NIBIOHN will develop immunoanalysis techniques employing next generation flow cytometers and other advanced technologies, and conduct clinical biomarking. Sumitomo Dainippon Pharma will carry out non-clinical and clinical study.

Through the joint research, the two parties aim to create highly innovative next-generation vaccine that protects against various subtypes of influenza involving not only seasonal but also pandemic influenza.

- * The joint research has been selected as a Fiscal 2019 general R&D-type project under the Cyclic Innovation for Clinical Empowerment (CiCLE) Program (4th invitation to participate) conducted by the Japan Agency for Medical Research and Development (AMED).
(Project name "Research and Development of Universal Influenza Vaccine"; Representative Organization: Sumitomo Dainippon Pharma)

Reference

TLR7 agonist adjuvant-containing vaccine formulations (DSP-0546LP)
Adjuvant enhances, re-directs, and/or sustains the immune responses to a co-administered antigen. DSP-0546LP is a formulations containing adjuvant activating TLR7, a toll-like receptor

that triggers innate immune responses on sensing viral RNA.

Next generation flow cytometer

A next generation flow cytometer is an innovative automated cell analysis and isolation device that can detect and separate single cells, which have been laser-irradiated and labeled with fluorescent antibodies or fluorescent substances. This device enables such cells to be analyzed with high accuracy and it is expected to achieve the highly sensitive detection of biomarkers, which can be used to predict the safety and efficacy of new vaccines.

Cyclic Innovation for Clinical Empowerment (CiCLE)

As a project of the Japan Agency for Medical Research and Development (AMED), the Cyclic Innovation for Clinical Empowerment (CiCLE) aims to formulate an innovative infrastructure (including human resources) for accelerating promotion of research and development and practical use of drug discovery activity outcomes in ways that precisely match the needs of medical professionals, and to create an environment in which development of open innovation ventures in medical research and development is empowered by uniting Japan's collective strengths through industry-university-government cooperation.

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma defines its corporate mission as "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide." By pouring all our efforts into the research and development of new drugs, we aim to realize our corporate mission and provide innovative and effective pharmaceutical solutions to people not only in Japan but also around the world. Sumitomo Dainippon Pharma's goal is to create innovative pharmaceutical products in the focus research areas of Psychiatry & Neurology, Oncology and Regenerative Medicine/Cell Therapy. For further details, visit <https://www.ds-pharma.com>.

National Institutes of Biomedical Innovation, Health and Nutrition

The National Institutes of Biomedical Innovation, Health, and Nutrition (NIBIOHN) was established in April 1, 2015 by integrating the National Institute of Biomedical Innovation and the National Institute of Health and Nutrition. A feature of the research carried out by NIBIOHN is that it covers many different areas ranging from medicine to health science. Our position as a National Research and Development Agency is to achieve the maximum benefits from research and development in order to contribute to the robust development of the national economy and the public good by raising the levels of science and technology. For further details, visit <https://www.nibiohn.go.jp/en/>.

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