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

Interim Analysis of Phase 1 Clinical Study on Novel Universal Influenza Vaccine Candidate Formulated with Sumitomo Pharma's Proprietary TLR7 Adjuvant (DSP-0546)

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Toru Kimura; "Sumitomo Pharma") and National Institutes of Biomedical Innovation, Health and Nutrition (Ibaraki, Osaka, Japan; President: Yusuke Nakamura; "NIBN") have been working on the development of a universal influenza vaccine with prophylactic efficacy against a wide range of influenza viruses. This initiative utilizes DSP-0546, a proprietary TLR7 adjuvant created by Sumitomo Pharma. Sumitomo Pharma and NIBN announced today that an interim analysis has been completed for the Phase 1 clinical study on "fH1/DSP-0546LP" ("the Formulation"), a universal influenza vaccine candidate, which was commenced on May 14, 2024.

The prespecified interim analysis was conducted in accordance with the protocol and confirmed generally favorable tolerability based on follow-up observations conducted up to four weeks after the final dose. Evaluation of immunogenicity, the key indicator of efficacy, is also currently underway as part of the interim analysis.

The Phase 1 study will continue with follow-up observations extending to one year post-administration. Sumitomo Pharma and NIBN remain committed to advancing research and development toward the early practical application of the universal influenza vaccine.

(Features of the Formulation)
Conventional influenza vaccines lose effectiveness due to viral mutations, making it necessary to select strains and produce vaccines to immunize against the strains predicted to circulate each year. They may also not respond well to emerging strains of influenza.
The Formulation was demonstrated to have broad cross-protection against antigenically different influenza viruses in pre-clinical studies. Sumitomo Pharma and NIBN now aim to commercialize it as a game-changing, next generation vaccine that is effective against not only seasonal influenza but also novel and potentially pandemic strains.

*Sumitomo Pharma and NIBN have been carrying out their joint research as a research and development project under the Cyclic Innovation for Clinical Empowerment (CiCLE) program conducted by Japan Agency for Medical Research and Development (AMED).

*Sumitomo Pharma and NIBN issued the following press release related to this matter.
“Start of Phase 1 Clinical Study on Novel Universal Influenza Vaccine Candidate”: https://www.sumitomo-pharma.com/news/20240514-2.html

Reference

TLR7 adjuvant (DSP-0546LP)

TLR7 adjuvant (DSP-0546LP) is a formulation containing a compound that specifically activates the Toll-like receptor 7 (TLR7), one of the TLR family members, which senses virus-derived RNA and induces innate immune responses. When added to antigens as an adjuvant, it enhances the quantity, quality, and durability of immune responses.

Cyclic Innovation for Clinical Empowerment (CiCLE)

Cyclic Innovation for Clinical Empowerment (CiCLE) is a program operated by Japan Agency for Medical Research and Development (AMED) that aims to create innovative infrastructure (including human resources) for accelerating research and development and drug discovery in ways that precisely match the needs of medical professionals, and to create an environment fostering open innovation and ventures in medical research and development by uniting Japan's collective strengths through industry-academia -government cooperation.
For further information, visit https://www.amed.go.jp/en/program/index07.html
Titled “Research and Development of Universal Influenza Vaccine” (Representative Organization: Sumitomo Pharma), the joint research being conducted by Sumitomo Pharma and NIBN was selected through the 4th open call for R&D proposals by the CiCLE in 2019.

Contact:
Corporate Communications, Corporate Governance
Sumitomo Pharma Co., Ltd.
E-mail：prir@sumitomo-pharma.co.jp

Planning Division, Department of Strategy and Research Support
National Institutes of Biomedical Innovation, Health and Nutrition (NIBN)
E-mail：pr@nibn.go.jp