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

Academic Conference Presentation on the Results of Phase 1 Clinical Study in Europe on a 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. Following the announcement on May 14, 2024, regarding the initiation of the Phase 1 clinical study in Europe ("the Study") of the universal influenza vaccine candidate "fH1/DSP-0546LP" ("the Formulation"), Sumitomo Pharma and NIBN today announced that the interim analysis results of the Study were presented by NIBN at the 29th Annual Meeting of the Japanese Society for Vaccinology and the 66th Annual Meeting of the Japanese Society of Clinical Virology (Joint Academic Conference held on September 27–28, 2025). The presentation included findings from non-clinical pharmacology studies.

The Study is a randomized, double-blind, placebo-controlled study enrolling 144 healthy adults between the ages of 18 and 45, designed to evaluate the safety, tolerability, and immunogenicity of the Formulation. Participants received two intramuscular doses at three-week intervals (Day 1 and Day 22) of one of the following: the Formulation (fH1 at 2 μg or 8 μg and DSP-0546LP at 2.5 μg, 5 μg or 10 μg), the antigen (fH1 at 2 μg or 8 μg alone), the adjuvant (DSP-0546LP at 2.5 μg, 5 μg or 10 μg alone), or placebo. The interim analysis was conducted as prespecified in the clinical study protocol and evaluated follow-up observations up to four weeks after the final dose (Day 50).
Although solicited adverse events* were observed in many participants, no serious safety concerns were identified, and overall tolerability was confirmed to be generally favorable. The most frequently reported solicited adverse events were injection site pain and headache. In the evaluation of immunogenicity, the geometric mean titers (GMT) of anti-LAH antibodies on Day 50 were higher in each dosage group of the Formulation compared to the placebo group. Additionally, the geometric mean fold increase of anti-LAH antibody titers from Day 1 to Day 50 was also higher in the Formulation groups than in the placebo group. Furthermore, compared to each antigen-alone group, the Formulation groups showed higher GMT of anti-LAH antibodies.

The Study will continue with follow-up observations extending to one-year post-injection. Exploratory endpoints such as cross-reactivity and antibody-dependent cellular cytotoxicity are also being evaluated. Sumitomo Pharma and NIBN remain committed to advancing research and development toward the early practical application of the universal influenza vaccine.

*Solicited adverse events observed within seven days following injection included the following:
Systemic adverse events (feverishness, chills, myalgia, fatigue, headache, nausea, arthralgia, malaise)
Local adverse events (injection site pain, erythema, redness, induration, swelling, warmth, pruritus)

(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.

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