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

**Topline Results from the Final Analysis of the Phase 1 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"), together with Dr. Takuya Yamamoto, Director of the Center for Intractable Diseases and ImmunoGenomics at National Institutes of Biomedical Innovation, Health and Nutrition (Ibaraki, Osaka, Japan; President: Yusuke Nakamura; "NIBN"), and Dr. Ayae Nishiyama, Senior Research Fellow in the Laboratory of Precision Immunology at the same center, announced today the topline results from the final analysis of the Phase 1 study in Europe (the "Study") of the investigational universal influenza vaccine candidate formulation "fH1/DSP-0546LP" (the "Formulation"). The final analysis included follow-up observations through one year after administration.

Taken together, the findings from the Study demonstrated its generally favorable safety and tolerability profile, favorable immunogenicity, cross-reactivity of the induced antibodies, and favorable qualitative characteristics of the immune responses. The increase in anti-LAH antibody titers was also generally maintained through one year after administration. Based on these findings, Sumitomo Pharma and NIBN will continue to advance research and development toward the practical application of a universal influenza vaccine.

The Study was a randomized, double-blind, placebo-controlled study enrolled 144 healthy adults between the ages of 18 and 40. 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. Analyses of the Study were conducted in accordance with a prespecified statistical analysis plan. Based on the interim analysis through four weeks after completion of dosing (Day 50), the results for the primary endpoints of safety and tolerability, the secondary endpoint of immunogenicity, and the exploratory endpoint of cross-reactivity had previously been reported. The final analysis of safety, tolerability, and immunogenicity through one year after administration has now been completed. In addition, new results have been obtained from exploratory analyses of the IgG subclasses and neutralizing activity of the induced antibodies.

No major safety concerns were identified through Day 50 in the previously reported interim

analysis. Consistent with these findings, no new major safety concerns were identified in the follow-up assessment on Day 386 as part of the final analysis, and a generally favorable tolerability profile for the Formulation was observed through one year after administration.

In the interim analysis, the Formulation group showed higher anti-LAH antibody titers than the placebo group and the antigen-only formulation group, and cross-reactivity was observed against LAH derived from the H5N1 subtype as well as LAH derived from the H1N1 subtype. The final analysis demonstrated that anti-LAH antibody titers in the Formulation group remained higher on Day 386 than on Day 1.

Further exploratory analyses were conducted on the IgG1-4 subclasses of anti-LAH antibodies. The geometric mean fold rise (GMFR) of IgG1 antibodies from Day 1 to Day 50 was 27.04-fold in the Formulation group receiving fH1 8 µg/DSP-0546LP 5 µg, compared with 11.93-fold in the antigen-only formulation group receiving fH1 8 µg.

In addition, exploratory analyses of the neutralizing activity of the induced antibodies against the H1N1 strain A/California/7/2009 showed GMFRs from Day 1 to Day 29 of 10.37-fold in the Formulation group receiving fH1 8 µg/DSP-0546LP 5 µg and 6.93-fold in the antigen-only formulation group receiving fH1 8 µg. The corresponding GMFRs were 0.94-fold in the placebo group and 1.59-fold in the adjuvant-alone group receiving DSP-0546LP 5 µg.

(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. Consequently, rapid responses to emerging influenza strains remain challenging.

The Formulation has shown broad cross-protection against antigenically different influenza viruses in pre-clinical studies. Sumitomo Pharma and NIBN aim to continue development for practical application as an innovative 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 releases 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>

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

<https://www.sumitomo-pharma.com/news/20250731-3.html>

“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)”:

<https://www.sumitomo-pharma.com/news/20251001.html>

“Interim Analysis (Cross-Reactivity) of Phase 1 Clinical Study in Europe on Novel Universal Influenza Vaccine Candidate Formulated with Sumitomo Pharma’s Proprietary TLR7 Adjuvant (DSP-0546)”:

<https://www.sumitomo-pharma.com/news/20260226-2.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.

IgG Subclasses

IgG antibodies comprise four subclasses, namely IgG1, IgG2, IgG3, and IgG4, each of which plays distinct roles in immune function. Evaluation of the subclass distribution provides insights not only into the magnitude of the antibody response but also into the qualitative characteristics of the induced immune response. An IgG1-dominant antibody response represents one type of immune profile that may be associated with cellular immune responses and is used as an indicator in evaluating the functional immune responses induced by vaccination.

LAH (Long Alpha Helix)

A conserved, normally hidden antigenic region common across a broad range of influenza viruses. The Formulation contains a modified hemagglutinin antigen engineered to expose the LAH region.

H1N1 Subtype

A subtype of influenza A virus responsible for seasonal epidemics each year. It is also known for the global pandemic caused by a novel H1N1 virus in 2009.

H5N1 Subtype

An avian influenza A virus subtype that primarily infects wild birds and poultry. In humans, it causes severe symptoms such as high fever and pneumonia, with extremely high fatality rates, and is therefore classified as a highly pathogenic avian influenza virus.

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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<https://www.nibn.go.jp/en/contact/index.html>