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

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)

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Toru Kimura; "Sumitomo Pharma") together with Dr. Takuya Yamamoto, Director of 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 of Laboratory of Precision Immunology in the same center, 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 announce the interim analysis results of the Phase 1 clinical study in Europe (the "Study") on "fH1/DSP-0546LP" (the "Formulation"), a universal influenza vaccine candidate, for which initiation was announced on May 14, 2024. Following the results previously announced regarding the primary endpoints (safety and tolerability), this announcement focuses on the exploratory endpoint evaluating cross-reactivity.

The Study is a randomized, double-blind, placebo-controlled study enrolling 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. 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).

Cross-reactivity was assessed by ELISA (Enzyme-Linked Immunosorbent Assay), using the LAH31 monoclonal antibody*, which binds to LAH derived from multiple influenza subtypes and exhibits cross-protective activity, as the standard.
In the group administered fH1 8 μg / DSP-0546LP 5 μg, the concentrations of anti-LAH antibodies bound to both the influenza H1 and the highly pathogenic avian influenza H5 LAH on Day 50 increased compared with those on Day 1, with geometric mean values (95% confidence intervals) of 2,994.54 ng/mL (2,077.84–4,315.67) and 2,657.93 ng/mL (1,556.89–4,537.65), respectively.
Considering these findings, the Formulation was observed to induce not only anti-LAH

antibodies against the H1N1 influenza virus subtype, which circulates annually, but also binding antibodies to LAH derived from the highly pathogenic avian influenza H5N1 subtype.

The Phase 1 study will continue with follow-up observations extending to one year post-administration. Evaluation of additional exploratory endpoints, including antibody-dependent cellular cytotoxicity activity, is ongoing. Sumitomo Pharma and NIBN remain committed to advancing research and development toward the early practical application of a multi-subtype influenza vaccine capable of responding to multiple influenza virus subtypes.

*Reference for the standard: https://doi.org/10.1371/journal.ppat.1011554

(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 has shown 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
“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.co.jp/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.co.jp/news/20251001.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.

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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