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

# Start of Phase 1 Clinical Study on Novel Universal Influenza Vaccine Candidate

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; "Sumitomo Pharma") and National Institutes of Biomedical Innovation, Health and Nutrition (Ibaraki, Osaka, Japan; President: Yusuke Nakamura; "NIBIOHN") have been working on the development of a universal influenza vaccine with prophylactic efficacy against a wide range of influenza viruses. Sumitomo Pharma and NIBIOHN announced today that they have commenced a Phase 1 clinical study on "fH1/DSP-0546LP" ("the formulation"), a universal influenza vaccine candidate formulation, in Europe.

(Universal influenza vaccine)
The formulation is a next generation vaccine candidate formulation consisting of post-fusion hemagglutinin antigen, fH1, which is expected to be effective against a broad range of influenza viruses, and TLR7 adjuvant, DSP-0546LP, to enhance the quantity, quality, and durability of the immune response.

(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 resulting from the joint research of Sumitomo Pharma and NIBIOHN was demonstrated to have broad cross-protection against antigenically different influenza viruses in pre-clinical studies. Sumitomo Pharma and NIBIOHN 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 NIBIOHN 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).

Reference
Post-fusion hemagglutinin antigen
Hemagglutinin is a glycoprotein on the surface of influenza and other viruses, which facilitates the entry of the virus into cells at infection. Hemagglutinin (hemagglutinin

antigen) is the main component of vaccines. The hemagglutinin antigen used in the formulation is a hemagglutinin antigen of altered structure modified by exposing conserved regions common to a wide range of influenza viruses. Inoculation of the antigen into humanized immune system mouse model was observed to induce human cross-reactive antibodies capable of protection against multiple antigenically different influenza viruses.

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 NIBIOHN was selected through the 4th open call for R&D proposals by the CiCLE in 2019.

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The Sumitomo Pharma Group defines its 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.” The Group aims to fulfill this Mission by delivering innovative, effective pharmaceuticals and healthcare solutions not only to people in Japan but also all over the world through concerted efforts in research and development. For further information, visit: https://www.sumitomo-pharma.com

National Institutes of Biomedical Innovation, Health and Nutrition

National Institutes of Biomedical Innovation, Health and Nutrition was established on April 1, 2015 by integrating the National Institute of Biomedical Innovation and the National Institute of Health and Nutrition. It is positioned as a National Research and Development Agency aiming to contribute to the improvement of the health of the Japanese people by preparing

the foundation for the enhancement of technologies related to drugs and medical devices and by promoting public health. For further information, visit: https://www.nibiohn.go.jp/en/

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