



## **Notice Regarding the Inclusion of Nasal Vaccine Research and Development for Influenza Virus and SARS-COV2 / New Modality Research and Development Project by AMED**

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**OSAKA, Japan, August 31, 2023** - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that our research and development of intranasal vaccines against influenza viruses and SARS-COV2, utilizing a cationic nanogel delivery system (cCHP), has been adopted into the vaccine / new modality research and development project that forms part of a public solicitation by the Advanced Research and Development Strategy Center (SCARDA<sup>a</sup>) of the Japan Agency for Medical Research and Development (AMED<sup>b</sup>).

Regarding the research and development of the nasal vaccine as adopted, we are going to pursue research including the optimization of vaccine composition and elucidation of immune mechanisms in cooperation with Chiba University Hospital<sup>1</sup> and the National Institute of Infectious Diseases. This three party network system can conduct all aspects required, spanning basic research through clinical development and manufacturing, to create nasal vaccines that are effective in preventing infection and to promptly provide them to society.

A nasal vaccine has the merits of being noninvasive, of being able to effectively induce antibody production in the respiratory mucosa, the site of initial infection, which are difficult to induce with conventional intramuscularly injected vaccines. Therefore, nasal vaccination is expected not only to prevent the onset and decrease the severity of infectious disease symptoms, but also to prevent the initial viral infection itself. Shionogi has signed a license agreement for a *Streptococcus pneumoniae* vaccine and SARS-COV2 vaccine by cCHP with HanaVax, which has strengths in nasal vaccine delivery technology<sup>1,2</sup>. We will also use this technology in the nasal vaccine research and development adopted this time.

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" as our key focus. We are not only conducting research and development of novel therapeutics, but we are also working towards total care, through building awareness, epidemiologic monitoring, prevention, diagnosis, and addressing exacerbations, as well as treating the infection itself. As a leading company in infectious diseases, we will continue to actively address a range of pathogenic threats, through research and development not only of therapeutic drugs, but also of preventive vaccines.

### **【About SCARDA】**

SCARDA is an organization established within the Japan Agency for Medical Research and Development (AMED) in March 2022. Based on the "Vaccine Development / Production System Strengthening Strategy" decided by the Cabinet in June 2021, it was organized for the purpose of strengthening the R&D / production system during normal times so it will be ready in times of pandemic emergency. AMED boosts the funding capacity for strategically significant research, initiative for world-leading vaccine research and development centers and promotes the strengthening of the pharmaceutical startup ecosystem. Please see [SCARDA website](#) for details.

### **【About HanaVax's cationic nanogel delivery system (cCHP)】**

Mucosal immunity is of great importance for the prevention of respiratory system infections because the respiratory mucosa is the first line of defense against pathogens. HanaVax's proprietary cationic nanogel delivery formulation provides a protective carrier for antigens consisting of a polysaccharide pullulan molecule modified with cholesterol and cationic amines. The nanogel increases the retention time of antigens on the mucosal surface and increases gradual uptake by immune cells. This effectively initiates the induction of both mucosal and systemic immunity. Please see [HanaVax's website](#) for details.

- a. SCARDA : Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response
- b. AMED : Japan Agency for Medical Research and Development

### **References**

- 1 : [Press release on February 10, 2022](#) [Shionogi Announces the Conclusion of a Contract for the Establishment of a Research Department for Mucosal Vaccines with Chiba University Hospital.]
- 2 : [Press release on September 30, 2020](#) [Shionogi and HanaVax Enter into a License Agreement for *Streptococcus Pneumoniae* Vaccine Candidate]
- 3 : [Press release on July 19, 2021](#) [Shionogi and HanaVax Enter into a License Agreement for COVID-19 Vaccine Development Using Cationic Nanogel Delivery System]

### **Forward-Looking Statements**

*This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.*

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