

Shionogi and HanaVax Enter into a License Agreement for COVID-19 Vaccine Development Using Cationic Nanogel Delivery System

Osaka and Tokyo, Japan, July, 19, 2021 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) and HanaVax Inc. (Head Office: Tokyo, Japan; President & CEO: Mizuhiro Ishimaru; hereafter “HanaVax”), a drug-discovery venture company originating from the University of Tokyo, announced they have entered into a license agreement for development of novel nasal vaccine candidates for COVID-19 using HanaVax’s cationic nanogel delivery system (cCHP)^{1,2,3}.

cCHP is HanaVax's unique delivery technology using cationic cholesteryl group-bearing pullulan. When administered intranasally, it can effectively induce immunity in the respiratory mucosa, and the whole body, without the pain caused by conventional injections. In emerging countries where the medical environment is not well established, it may be difficult to administer vaccines by injection, and from the viewpoint of medical access, there is an increasing need for a nasal vaccine as an easy-to-use preparation globally.

Shionogi and HanaVax signed a license agreement for a *Streptococcus pneumoniae* nasal vaccine last year⁴. With this new agreement, Shionogi is granted exclusive global rights to research, develop, manufacture, distribute, and commercialize COVID-19 nasal vaccines using cCHP technology. HanaVax will receive an upfront payment and milestones relating to future development progress, as well as royalties based on net sales of the vaccine.

Shionogi and HanaVax will advance research and development of an innovative, next generation nasal vaccine to protect people from the threat of COVID-19, by combining Shionogi’s expertise in infectious diseases with HanaVax’s pioneering research and technology related to mucosal immunity.

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.

About Shionogi

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" as our key focus. We are not limiting ourselves to the research and development of therapeutic medications, but are also focused on the total care of infectious disease, through awareness building, prevention, diagnosis, and treating exacerbations, as well as the infection itself. For more information, please visit <https://www.shionogi.com/global/en/>.

About HanaVax

HanaVax is a drug discovery biotechnology startup founded with the mission to "Developing nasal vaccines for a healthier society". The proprietary nasal vaccine that is the subject of this license was developed on the basis of ten years of collaborative research between two pioneers of mucosal immunity and chemical engineering in the service of improved drug and vaccine delivery, Distinguished Prof. Dr. Hiroshi Kiyono (The University of Tokyo and Chiba University) and Prof. Dr. Kazunari Akiyoshi (Kyoto University). For more information, please visit <https://www.hanavax.co.jp/en/>.

Reference

1. Nochi T. et.al., "Nanogel antigenic protein delivery system for adjuvant-free intranasal vaccines" *Nature Materials*, **2010**, 9, 572-578. <https://www.nature.com/articles/nmat2784>
2. Yuki, Y et.al., Physicochemical characterization of protein-based pneumococcal nasal vaccine formulation using adjuvant-free intranasal nanogel delivery system. *Mol Pharma* 2021, 18 : 1582-1592. <https://doi.org/10.1021/acs.molpharmaceut.0c01003>
3. Nakahashi-Ouchida R. et.al., A Nanogel-based Trivalent PspA Nasal Vaccine Protects Macaques from Intratracheal Challenge with Pneumococci. *Vaccine* 2021, 39:3353-3364. <https://doi.org/10.1016/j.vaccine.2021.04.069>
4. [Press Release on September 30, 2020](#), Shionogi and HanaVax Enter into a License Agreement for *Streptococcus Pneumoniae* Vaccine Candidate

Press Release



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.

For Further Information, Contact:

SHIONOGI Website Inquiry Form : <https://www.shionogi.com/global/en/contact.html>

HanaVax Inc. Website Inquiry Form : <https://en.hanavax.co.jp/contact>