



## **Study of powder-based intranasal mucosal vaccine system applicable to induce antiviral IgA production**

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Currently adopted intramuscular/subcutaneous vaccines against respiratory infections effectively prevent disease development and reduce hospitalization. However, they are not meant to induce sterilizing immunity and cannot block horizontal pathogen spread. Live attenuated vaccines can block pathogen entry, but intranasal administration demands reclining and causes some symptoms of infection. Inactivated and subunit vaccines are safer and have been shown to induce the production of secretory IgA and immune protection in small animal experiments; however, unlike rodents, humans lack lymphoid tissues associated with nasal mucosa. Thus, non-human primates must be utilized to prove intranasal vaccines' possible efficacy against respiratory infections. At Shin Nippon Biomedical Laboratories, Ltd., we have developed a powder-based intranasal drug delivery system that showed safety and efficacy through clinical trials. Taking advantage of the above system's capabilities in delivering inert powder vehicles into nasal cavity as well as the availability and years of experience in handling primate models, we intend to develop a powder-based intranasal vaccine system that can induce mucosal IgA production and sterilizing immunity against respiratory viral infections. The use of an adjuvant is crucial to induce long-lasting mucosal IgA production with a protein antigen. We have candidates of nanoparticle-based adjuvants that will be modified to induce effective IgA memory responses along with protein antigens. When accomplished, this powder-based mucosal vaccine system will provide easier distribution and storage without requiring cold chains and needle-free administration without causing uncomfortable symptoms of live virus replication.

Our goal is to prove this concept in non-human primate models by vaccinating animals with the powder-based and nanoparticle-adjuvanted system and exposing them to the pathogenic influenza virus. After proving the above concept and showing the safety of the powder-based vehicle and nanoparticle adjuvant, we hope to proceed to a phase 1 clinical trial.

This system, when proven effective, can be applicable not only to various respiratory infections but also to other mucosal infections, including those caused by intestinal and genital pathogens.