Development of combined inactivated intact virus particle vaccine to influenza and corona virusinfection

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The synchronous circulation of seasonal influenza viruses and SARS-CoV-2, the causative agent of COVID-19, poses a remarkable threat to public health. Given the continuous and unpredictable emergence of new variants from both viruses, there is a need for routine vaccination for influenza and COVID-19 and to prevent the spread of both diseases. To address this issue, we developed inactivated intact virus particle vaccines for influenza and COVID-19 that retain the structure of the virus to generate immune responses analogous to those against actual infection.

However, the marked loss of SARS-CoV-2 spike proteins during the process of cultivation, inactivation, and purification of virus, has impeded the development of an inactivated COVID-19 vaccine with potent immunogenicity. Therefore, we explored proper conditions and established a method for producing inactivated intact virus particle vaccine with optimum retention of spike proteins. A single dose of the co-formulated two-in-one inactivated intact virus particle influenza/COVID-19 vaccine, protected mice from both infections without the addition of adjuvants. The present results indicate that inactivated intact virus particle vaccine is a safe and effective modality that can be utilized for the future pandemics.

Since 2015, we have been collaborating with vaccine manufacturers to develop the inactivated intact virus particle vaccine for seasonal influenza. The inactivated intact virus particle vaccine was manufactured under GMP and evaluated for immunogenicity using mice and cynomolgus macaques. The vaccine primed naive animals and induced sufficient cellular as well as humoral immunity without adjuvants and with one-half the antigen dose of the current seasonal influenza vaccine. Moreover, it showed no apparent adverse events in a clinical trial.

Furthermore, a co-formulated two-in-one inactivated intact virus particle influenza/COVID-19 vaccine has demonstrated promising results in mice. Since KM Biologics is developing an inactivated vaccine for COVID-19, facilities are ready to utilize for the production of inactivated intact virus particle vaccines for influenza and COVID-19.

In the present proposed program, we will conduct pre-clinical studies and Phase I and II clinical trials for a co-formulated two-in-one inactivated intact virus particle influenza/COVID-19 vaccine that can prevent influenza and COVID-19 simultaneously.