Sanofi Pasteur proves the excellence of Vero cell culture-derived Japanese encephalitis vaccine Imojev through global and domestic clinical trials

- Sanofi Pasteur holds a roundtable to inform media on the release of Japanese encephalitis vaccine Imojev -
- Simple 2-shot schedule for infant, 1 shot for adult -

[May 27, 2015, Seoul] - Sanofi Pasteur, the vaccine division of Sanofi, held a roundtable on 27 May to inform media on the release of its Japanese encephalitis (JE) vaccine Imojev: the company also confirmed the efficacy and superiority of Imojev by sharing the latest advances of JE and the global and domestic clinical trial results.

Dr. Choi, medical advisor of Sanofi Pasteur, who gave a presentation on the topic of "The latest advancements and prevention of JE," said, "As one of the most important causes of encephalitis in the Asian region, approximately half of the 3.4 billion world population are exposed to the risk of the JE infection, and more than 60,000 cases in various clinical stages from mild symptom with a fever to encephalitis are annually reported in Asia." In fact, the onset of JE is usually accompanied with high fever, seizure and unconsciousness, and the disease has about 30% of mortality rates. As it also develops complications in the central nervous system, it requires greater need for prevention.

Dr. Choi continued, "Korea, which adopted the national mandatory vaccination for JE in the 1980s, introduced various vaccines starting with a mouse brain-derived inactivated vaccine in 1967. Imojev, which was released after obtaining the approval of Ministry of Food and Drug Safety last month, is a live attenuated vaccine developed through the WHO-recommended Vero cell culture-derived method. With a small amount of antigen, it can prevent JE and form protective immunity with only one shot for primary injection and a booster in case of children."

Dr. Bang, medical advisor of Sanofi Pasteur, explained about the domestic basic vaccination research conducted on healthy infants between 12 to 24 months of age by stating, “this study confirmed Imojev's excellent safety by verifying a high level of geometric mean titre
that guarantees 100% immune response\(^1\) and long-term protection effect 28 days after the booster injection on healthy infants aged between 12 to 24 months, in addition to verifying the 100% immune response\(^1\) 28 days after a single-dose administration of Imojev."

Talking specifically about a clinical trial conducted on adults over the age of 18 in Australia and the US, Dr. Bang added, "\textit{Imojev showed fast and high prevention effect}\(^8\) only 2 weeks after administration. With its highly immunogenic responses and placebo-level safety, \textit{Imojev not only boasts more outstanding tolerability}\(^9\) than that of the mouse brain-derived inactivated JE vaccine, but also offers long-term protection effect\(^10\) only with a single-dose administration."

Regis Launay, the GM of Sanofi Pasteur Korea, said, "\textit{Sanofi Pasteur has been contributing to the improvement of human health through the development of innovative vaccines for the past 110 years. We will lead the prevention towards JE in all ages with Imojev with the enhancement of schedule convenience with one or two-dose administration.}"

Sanofi Pasteur passed the WHO’s pre-qualification testing of Imojev in September last year and about 1 million doses of Imojev have already been administered in Asia Pacific since its launch in 2012.

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\textbf{About Imojev}

Imojev is a Vero cell culture-derived\(^4\) live vaccine against Japanese encephalitis that was developed following the recommendation of the World Health Organization. Unlike mouse brain or hamster kidney-derived live vaccines, it lowers the risk of contamination that can take place while producing vaccines using animal cells.

High level of protection is induced following a single dose in adults\(^6\) (18 years of age and above) while a booster dose is recommended for infants from 9 months of age.\(^1\)\(^7\) Moreover, as it is thimerosal-, gelatin-, and antibiotics-free, the risk of adverse effects is decreased.\(^1\)\(^1\) Following the recommendation of the WHO in 2005, Japan, an area at risk for Japanese encephalitis, fully suspended the use of the mouse brain-derived inactivated vaccine. Other advanced countries are gradually replacing the JE vaccine with Vero cell culture-derived vaccines.\(^1\)\(^3\)\(^1\)\(^4\)
About Sanofi Pasteur

Sanofi Pasteur, the vaccines division of Sanofi, provides more than 1 billion doses of vaccine each year, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur offers a broad range of vaccines protecting against 20 infectious diseases. The company's heritage, to create vaccines that protect life, dates back more than a century and every day, the company invests more than EUR 1 million in research and development. Sanofi Pasteur Korea was established in 1997, and is one of main vaccine providers in Korea.

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