Proprietary Adjuvant System Induces Improved Immune Response vs. Conventional Formulation

GlaxoSmithKline’s (GSK) candidate vaccine for the prevention of cervical cancer formulated with proprietary AS04 adjuvant system claims to have better immune response compared with the vaccine formulated with conventional aluminum salt adjuvant.

Data from the first studies to directly compare two different adjuvanted formulations of GSK’s candidate vaccine for the prevention of cervical cancer revealed that the immune response induced by the vaccine formulated with the proprietary AS04 adjuvant system was consistently stronger and more sustained, at every evaluated timepoint, than that observed with the same vaccine formulated with conventional aluminum salt adjuvant. The results were maintained for at least 3.5 years post-vaccination.[1]

These data, published in Vaccine, showed that GSK’s cervical cancer candidate vaccine formulated with the AS04 adjuvant system not only induced higher and more sustained antibody levels against HPV 16 and HPV 18 but also a more robust immune memory response — specifically, in consistently higher observed numbers of HPV 16/18-specific memory B cells — compared to that observed after vaccination with the aluminum formulation. GSK’s cervical cancer candidate vaccine is under study for protection against pre-cancerous lesions and cervical cancer caused by HPV 16 and HPV 18, and in previously published studies, the vaccine formulated with the AS04 adjuvant system has shown, in all vaccinated women, 100 per cent protection against pre-cancerous lesions caused by HPV 16 and/or 18 over a 4.5 year period.[2][3]

“For a cervical cancer vaccine to be effective, it must induce a strong immune response and provide protection that lasts. These new data demonstrate a genuine immunological effect of the AS04 adjuvant system by contributing to a strong and sustained vaccine-induced immune response of high quality. Formulating our candidate vaccine with this proprietary adjuvant system further supports GSK’s ambition to developing the best possible vaccine for the prevention of cervical cancer in women of all ages,” commented Dr Philippe Monteyne, Head of Global Vaccine Development of GSK Biologicals.

About GSK’s proprietary AS04 adjuvant system

GSK’s cervical cancer candidate vaccine is formulated with the proprietary adjuvant system AS04 that was developed with the goal of inducing strong and sustained immune responses. AS04 is composed of aluminum salt and monophosphoryl lipid A (MPL); MPL is an immunostimulant capable of directly activating key immune mechanisms,
which will ultimately enhance the immune response to the antigens included in the vaccine.

Adjuvants are substances, which when used in combination with antigens in vaccines, enhance the immune response. The use of adjuvants in vaccines, conventionally formulated only with aluminum salt, is very common.

About the study

In these studies, GSK’s cervical cancer candidate vaccine formulated with the AS04 adjuvant system and a vaccine containing the same antigens and formulated with aluminum salt only were compared to assess the quality and durability of the immune response generated after vaccination. The studies were conducted in a variety of settings, including in animals, in vitro, and in humans.

Each of the separate methods used in the studies included a three-dose course of GSK’s cervical cancer candidate vaccine formulated with either the AS04 adjuvant system or aluminum adjuvant only (at 0, 1 and 6 months). Antibody levels and memory B cells were measured over a total period of 4 years.

Results in human subjects showed that antibody levels induced by the HPV vaccine formulated with the AS04 adjuvant system were 1.5 to 2.1 times higher for HPV 16 and HPV 18 respectively than those induced following vaccination with the aluminum formulation at 4 years.

These data also demonstrate the potential ability of the AS04 adjuvanted vaccine to increase immune memory. Following vaccination with the AS04 formulation of GSK’s cervical cancer candidate vaccine, observed numbers of memory B cells were 2 to 3.6 times higher for HPV 18 and HPV 16 respectively than those observed with the aluminum formulation. Immune memory B cells have been shown to be essential to the persistence of antibody levels following vaccination.

The abstract for this study may be viewed online at: www.sciencedirect.com/science/journal/0264410X

About GSK’s cervical cancer candidate vaccine

GSK’s cervical cancer candidate vaccine has been developed to prevent infection and cervical lesions associated with the two most prevalent cancer-causing types of HPV, specifically HPV 16 and 18. In addition, GSK’s cervical cancer candidate vaccine has shown a potential to protect against infection with the third and fourth most prevalent cancer-causing types of HPV, namely types 45 and 31. HPV types 16, 18, 45 and 31 are collectively responsible for 80 percent of cervical cancers globally.

GSK’s submitted a marketing application for its cervical cancer candidate vaccine to the European Agency for the Evaluation of Medicinal Products (EMEA) in March 2006. Other international regulatory filings followed in Australia, parts of Asia and Latin America since March 2006 onwards, with submission to the U.S. Food and Drug Administration (FDA) targeted by the end of 2006.
About HPV and cervical cancer

Both younger and older women are at risk of cervical cancer due to new or subsequent infection by cancer-causing types of a common virus: HPV. Of the many different types of HPV that are cancer-causing, HPV types 16 and 18 together account for more than 70 percent of all cervical cancer cases globally.[4] Cervical cancer is a major global health problem, with nearly 500,000 new cases occurring each year worldwide.[5] It is the second most common cancer – and the third leading cause of cancer deaths – in women worldwide. Each year an estimated 270,000 women die from the disease, and it is the leading cancer killer of women in the developing world.

About GlaxoSmithKline and GlaxoSmithKline Biologicals

In the next five years, GSK expects to launch more major new vaccines: a vaccine against rotavirus (U.S.), a vaccine to prevent pneumococcal disease, an improved flu vaccine for the elderly, and a meningitis combination vaccine for infants. For company information please visit www.gsk.com.

GSK Biologicals (GSK Bio), a leading vaccine manufacturer, is headquartered in Rixensart, Belgium, and employs more than 1,500 scientists. In 2005, GSK Bio distributed more than 1.2 billion doses of vaccines to 165 countries in both the developed and the developing world, an average of more than 3 million doses per day.

References


Source: GSK.com