Overview of safety, immunogenicity and efficacy of GSKs cervical cancer vaccine candidate manufactured with the Baculovirus Expression Vector System (BEVS)

M Deschamps, Ph.D
GlaxoSmithKline Biologicals, Rixensart, Belgium

GlaxoSmithKline Biologicals (GSK) developed a cervical cancer vaccine candidate composed of HPV-16/18 L1 virus-like particles (VLP) adjuvanted with the proprietary AS04 adjuvant system. The vaccine L1 antigens are produced with the BEVS which uses a baculovirus as the carrier of the L1 gene and a cell line to express the L1 proteins. At the end of this process, L1 proteins are extracted and purified to self-assemble into VLPs. The BEVS allows for the production high quality, well-characterized, safe and scalable HPV vaccine.

GSK’s cervical cancer vaccine candidate has been evaluated for immunogenicity, efficacy and safety in eleven independent clinical trials that include approximately 30,000 women ages 10 years and above. Across all studies and age groups, the cervical cancer vaccine candidate has been shown to be generally safe and well-tolerated. The cervical cancer vaccine candidate demonstrated significant protection against CIN2+ attributed to HPV-16/18 infections in a broad population of women. Additionally, cross protection was shown against persistent infection with specific oncogenic HPV types (31, 45, 52). In females 10-55 years, we have observed a strong antibody response and high seropositivity (≥98%) for both HPV-16 and 18 antigens. Furthermore, antibody titers remained substantially higher than natural infection titers up to 4.5 years in women 15-25 years old.

The BEVS production process enables the large scale manufacturing of GSKs cervical cancer vaccine candidate and presents a suitable approach for eukaryotic systems in the manufacturing of efficacious, safe, and immunogenic HPV recombinant vaccines.