

CERVARIX

GlaxoSmithKline's Cervical Cancer Candidate Vaccine

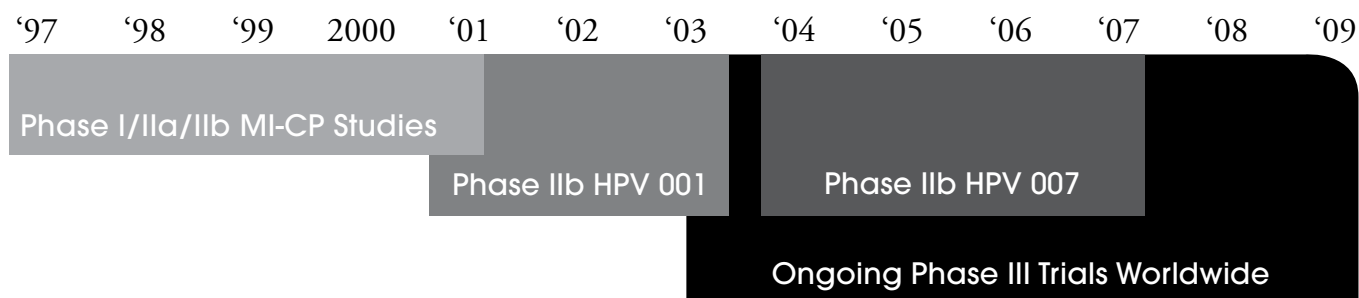
Media Backgrounder:

Scientific Background For Informational Purposes Only

GlaxoSmithKline's (GSK) cervical cancer candidate vaccine is currently undergoing clinical trials to determine its efficacy and safety in protecting women from cervical cancer. The candidate vaccine targets the cancer-causing human papillomavirus types 16 and 18, which are responsible for at least 70 percent of all cervical cancer cases worldwide.

GSK submitted a Biologics License Application to the U.S. Food and Drug Administration in March 2007 for CERVARIX®, the proposed name for the GSK cervical cancer candidate vaccine. The candidate vaccine has not yet been approved for use in the U.S.

GSK Cervical Cancer Candidate Vaccine Trials Timeline



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Phase I/IIa/IIb Trials

Study	Objective	Subjects
MI-CP044 (with MedImmune, Inc.)	Immunogenicity and safety	Women 18 to 30 years of age
MI-CP055	Adjuvant comparison and safety	Women 18 to 30 years of age
MI-CP057	Dose-range adjuvant comparison and safety	Women 18 to 30 years of age
MI-CP058	Assess safety	Women 18 to 30 years of age
Study 001	Efficacy and safety	Women 15 to 25 years of age
Study 007	Efficacy and safety	Women 15 to 25 years of age

Phase III Trials

Phase III studies are underway in 37 countries with more than 39,000 subjects planned.

Study	Objective	Subjects
Study 008 <i>Papilloma Trial to Prevent Cervical Cancer In Young Adults (PATRICIA)</i>	Efficacy and safety	Women 15 to 25 years of age
Study 009 <i>National Cancer Institute Supported Trial</i>	Efficacy and safety	Women 18 to 25 years of age
Study 010	Immunogenicity comparison of CERVARIX and Gardasil®	Women 18 to 45 years of age
Study 012	Immunogenicity and safety	Women 10 to 25 years of age
Study 013	Safety	Women 10 to 14 years of age
Study 014	Safety and Immunogenicity	Women 15 to 55 years of age
Study 015	Efficacy in preventing precancerous cervical lesions and safety	Women 26 to 55 years of age

Human Papillomavirus Phylogenetics and Additional Protection

Among the more than 100 formally described human papillomavirus types, up to 18 are known to cause cancer. Types 16 and 18 are the most common cancer-causing virus types. All cancer-causing virus types have some similarities, falling into phylogenetically, or biologically related, groups. For example types 16 and 31 share similarities, as do types 18 and 45. These similarities have led researchers to study whether protection from one cancer-causing virus type included in a vaccine may afford protection against a related type not included in that vaccine.

In a study published in 2006 in *The Lancet*, CERVARIX showed 100 percent efficacy over 4.5 years against precancerous lesions associated

with cancer-causing virus types 16 and 18. The study also showed protection against incident infection caused by cancer-causing virus types 45 and 31, the third and fourth most common cancer-causing virus types. The protection against infection with types 45 and 31 also extended over 4.5 years. Additional data up to 5.5 years will be presented in the near future at an appropriate medical meeting. Cancer-causing virus types 16, 18, 45 and 31 are collectively responsible for 80 percent of cervical cancers globally. GSK is conducting further large studies and analyses to determine the extent of this protection against infection with the cancer-causing human papillomavirus.

AS04: GSK's Novel Adjuvant

Proprietary vaccine technology designed for long-lasting protection

GSK has a proprietary adjuvant, AS04, which is designed to boost the immune response and increase the length of protection. Most vaccines include an adjuvant that is composed of aluminum salt alone. GSK's AS04 is unique because it is made with aluminum hydroxide and a novel substance called monophosphoryl lipid A (MPL®). MPL stimulates the immune system and is capable of directly activating key immune mechanisms. Ultimately, MPL enhances the immune response to antigens contained in the vaccine.

Studies have shown that GSK's cervical cancer candidate vaccine with AS04, when compared with the same GSK vaccine formulated with aluminum salt, sustains a stronger and longer immune response.