

Cervarix® har visat längst varaktig skyddseffekt av de godkända livmoderhalscervaccinerna mot HPV 16 och 18

Resultat publicerade i The Lancet bekräftar vaccinetts effekt på upp till 6,4 år mot de två vanligaste cancerframkallande virustyperna

3 December 2009: Resultat publicerade i The Lancet i dag visar att GlaxoSmithKlines Cervarix®, ger starkt och varaktigt skydd mot de två vanligaste virustyperna (humant papillomvirus, HPV) som orsakar livmoderhalscancer, HPV 16 och 18¹, upp till 6,4 år², den längsta uppföljningstiden av skyddseffekt som har dokumenterats i en effektstudie för något vaccin mot livmoderhalscancer fram tills idag.

HPV-007-studien visar att vaccinet gav 100 procent skyddseffekt mot cellförändringar (CIN 1 + och CIN 2 +) orsakade av HPV-typerna 16 och 18, hos kvinnor som fått minst en dos vaccin.³ Bland de kvinnor som studerades avseende immunogenicitet uppmättes höga nivåer av antikroppar mot HPV 16 och 18 hos över 98 procent av kvinnorna som fått Cervarix® i upp till 6,4 år, detta indikerar ett långvarigt immunsvär.²

Eftersom kvinnor fortsätter vara mottagliga för HPV-infektioner under hela sitt sexuellt aktiva liv är det oerhört viktigt att ett vaccin mot livmoderhalscancer ger långvarigt skydd. Forskningsresultaten som nu visar att Cervarix® ger skyddseffekt som inte avtar i upp till 6,4 år understryker GSK:s förtroende för AS04, adjuvanssystemet i vaccinet, vilket kan vara en viktig faktor för att vaccinet ger det långvariga och ihållande immunsvaret som observerats i den här studien. GSK kommer att fortsätta denna studie i 9,5 år för att ytterligare fastställa den långsiktiga effekten och säkerhetsprofilen för vaccinet.

Data från HPV-007 studien stödjer även tidigare kliniska data som visat vaccinetts korsskydd.² HPV 16 och 18 orsakar ungefär 50 procent av cellförändringar (CIN 2 + och CIN 3 +)²; i HPV-007-studien visade vaccinet en total effekt på 71,9 procent mot cellförändringar av typ CIN 2 +, vilket tyder på att vaccinetts skyddseffekt kan sträcka sig längre än skyddet mot HPV-typerna 16 och 18.²

Utöver effekten mot cellförändringar (CIN 1 + och CIN 2 +), visar resultat från denna studie att vaccinet ger hög effekt (96,7 procent) mot förändringar orsakade av HPV 16 och 18 som upptäckts via cellprov i screening.²

Barbara Romanowski från University of Alberta, Kanada - huvudprövare för studien och huvudförfattare till publikationen kommenterade: "Denna studie har genomförts bland unga kvinnor som tidigare inte varit infekterade med HPV - en grupp som bäst representerar flickor före sexuell debut och som är den typiska målgruppen för nationella vaccinationsprogram. Detta gör studieresultaten särskilt viktiga eftersom de visar att Cervarix® ger unga flickor ett omfattande skydd i minst 6,4 år mot de vanligast cancerframkallande HPV-typerna. Den effekt man observerade mot förändringar i prov som fångas upp genom screening är också viktig, eftersom dessa provsvar kan leda till oro bland kvinnor, remiss till specialist och kirurgiska ingrepp."

I studien var säkerhetsprofilen för Cervarix® jämförbar med placebo.² Cervarix® tolererades väl i studien.² Frekvensen av allvarliga biverkningar i gruppen som vaccinerats med Cervarix® var jämförbar med kontrollgruppens² och inkluderade depression, graviditet och perinatalt relaterade åkommor.³

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About HPV 007

- HPV 007 is an extended follow-up study of women who participated in the primary efficacy study (HPV 001) of GSK's cervical cancer vaccine *Cervarix*[®]
- The primary study was a double-blind, controlled trial of 1,113 young women, between 15-25 years of age, randomized to receive three doses of the GSK's vaccine formulated with the AS04 adjuvant system or, of a placebo (aluminium hydroxide) on a 0, 1 and 6 month schedule
- The extended follow-up study looked at a subset of 776 women for a period up to 6.4 years
- The trial was conducted in the US, Canada and in Brazil and evaluated the efficacy, safety and immunogenicity of *Cervarix*[®] for the prevention of HPV 16 and/or HPV 18 infections, as well as associated Pap smear abnormalities and cervical lesions
- In the extended follow up study, women were evaluated for HPV DNA using cervical samples and annual cervical cytology evaluations were performed. Women were referred for colposcopy following protocol guidelines
- The vaccine was shown to provide high and sustained protection against HPV types 16 and 18 for up to 6.4 years

About *Cervarix*[®]

Cervarix[®] was specifically designed with a proprietary adjuvant, AS04, to deliver high and sustained levels of antibodies aimed at providing broad and long-term protection against cervical cancer.⁴ It has been shown to be generally well tolerated. The most common symptoms after vaccination included pain, redness and swelling at the injection site, fatigue, fever, aching, headache, itching, rash or gastrointestinal disturbances.⁵

To date, *Cervarix*[®] has been approved in more than 100 countries around the world, including the 27 member states of the European Union (EU), United States, Japan, Australia, Brazil, South Korea, Mexico, Taiwan and South Africa. Licensing applications have been submitted in more than 20 additional countries. GSK also received prequalification for the vaccine from the World Health Organization (WHO) in July 2009.

The *Cervarix*[®] Summary of Product Characteristics can be found here:

<http://emc.medicines.org.uk/medicine/20204/SPC/Cervarix>

About HPV and cervical cancer

Women are at risk of HPV infection throughout their sexually active lives.⁶ Approximately 100 types of HPV have been identified to date⁷ and, of these, approximately 15 virus types are known to cause cervical cancer.⁸ HPV types 16 and 18 are responsible for approximately 70 percent of cervical cancers globally, with types 45, 31 and 33 the next three most common cervical cancer causing virus types after 16 and 18.^{1,9} Persistent infection with cancer-causing HPV types can lead to abnormal Pap smears, cervical pre-cancer and cervical cancer. Cervical intraepithelial neoplasia (CIN), graded as CIN 1, 2 and 3, refers to pre-cancerous cells found on the surface of the cervix. The higher the grading number, the higher the probability the abnormal cells will become cancer cells.¹⁰ CIN 1, 2 and 3 refers to mild, moderate or severe cell changes respectively. Worldwide, more than 500,000 women will be newly diagnosed with cervical cancer and 280,000 women will die from it each year.¹¹

HPV types 16, 18 and 45 are particularly important because these types are associated with nearly 90 percent of adenocarcinoma cases a very aggressive type of cervical cancer more common in younger women and more difficult to detect through screening.¹²

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