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## **CHMP GIVES POSITIVE OPINION TO ADJUVANTED GLAXOSMITHKLINE VACCINE, FENDRIX<sup>®</sup> TO PREVENT INFECTION FROM HEPATITIS B FOR SPECIFIC HIGH-RISK PATIENTS**

**London (England) and Rixensart (Belgium): Wednesday 27 October 2004:** Further to the filing for regulatory approval with the European Agency for the Evaluation of Medicinal Products (EMA) in May 2003, GlaxoSmithKline Biologicals (GSK Bio) has received a positive opinion from the Committee for Medical Products for Human Use (CHMP) of Europe dated 21 October 2004 for its adjuvanted hepatitis B vaccine, Fendrix<sup>®</sup>. The official approval is anticipated within 3 months. The EMA and CHMP operate similarly to the US FDA and FDA's Advisory Boards in reviewing and commenting on new products before they are approved for sale.

GSK Bio has a long history and commitment to the successful development of novel hepatitis vaccines including vaccines for hepatitis B, combination vaccines for hepatitis A and B and pediatric combinations containing hepatitis B. Fendrix<sup>®</sup> is under investigation for the prevention of hepatitis B in patients with renal insufficiency including specific high-risk groups such as pre-haemodialysis and haemodialysis patients, from 15 years of age onwards.

Fendrix<sup>®</sup> includes the GSK Bio Hepatitis B antigen and a novel proprietary GSK Bio adjuvant, AS04, which in turn contains MPL<sup>®</sup> adjuvant from Corixa. Adjuvants are formulated compounds or additives, that combined with vaccine antigens, help to boost the body's immune system.

MPL<sup>®</sup> adjuvant is a component in GSK Biologicals novel, proprietary adjuvant systems used in a number of key future vaccines from GSK Bio including a vaccine under investigation for the prevention of cervical cancer and a vaccine under investigation for the prevention of genital herpes which are both in phase III of clinical development. MPL<sup>®</sup> is also included in the adjuvant system of GSK Bio's malaria vaccine, which recently showed proof of concept in a phase IIb clinical trial in 1 to 4 year olds in Africa.

"Adjuvants have become an important component in many of GSK Bio's most promising vaccines under development and we have developed a range of novel proprietary adjuvant systems including MPL<sup>®</sup>. With this new hepatitis B vaccine under study for specific high-risk groups, we have demonstrated a persistence of antibodies and expect this to also be of importance for two of our vaccines under study for the prevention of cervical cancer and for the prevention of genital herpes" said Jean Stéphenne, president of GlaxoSmithKline Biologicals.

## **GLAXOSMITHKLINE BIOLOGICALS**

GlaxoSmithKline Biologicals (GSK Bio), one of the world's leading vaccine manufacturers, is located in Rixensart, Belgium, which is the centre of all GlaxoSmithKline's activities in the field of vaccine research, development and production. GSK Bio employs more than 1000 research scientists, who are devoted to discovering new vaccines and developing more cost-effective and convenient combination products to prevent infections that cause serious medical problems worldwide. GSK Bio future vaccine pipeline contains more than 20 new vaccines in clinical development.

In 2003, GSK Bio distributed more than 850 million doses of vaccines to 152 countries in both the developed and the developing world – an average of 27 doses per second. Of those vaccine doses, approximately 85 million were doses of combination paediatric vaccines, which protect the world's children against a minimum of three – and as many as six – diseases in one vaccine. For more information, visit GlaxoSmithKline's vaccine websites at [www.gsk-bio.com](http://www.gsk-bio.com) and [www.worldwidevaccines.com](http://www.worldwidevaccines.com) (for medical professionals).

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

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