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**Three Clinical studies give GlaxoSmithKline's
Cervical Cancer vaccine- Cervarix™ a clear edge**

NEW DELHI, JULY 17 2009: **GlaxoSmithKline Pharmaceuticals Limited (GSK)** today shared the results of three recently published Clinical Studies, conducted for its Cervical Cancer vaccine- **Cervarix™**. The findings shared on Cervarix™ confirmed that the vaccine:

- (1) Offers protection against five of the most common cancer-causing virus types,
- (2) Generates significantly higher immune response compared to the other available vaccine, Gardasil® and
- (3) Provides high and sustained antibody levels for at least 7.3 years till date.

Dr. Hasit Joshipura, Vice President, South Asia and Managing Director, GlaxoSmithKline Pharmaceuticals, India said, "We are pleased with the new findings which confirm the importance of the role of Cervarix™ in helping protect women against Cervical Cancer."

Results from the **largest global efficacy trial of a cervical cancer vaccine**, involving 18,644 women and published in The Lancet showed that Cervarix™ offers Protection' against the **five most common cancer-causing virus types**. The study confirmed that GlaxoSmithKline's Cervarix™ is not only highly effective at protecting against the two most common cervical cancer-causing human papillomavirus (HPV) types, 16 and 18, but also provides **additional cross-protection** against HPV types 31, 33 and 45, the three most common cancer-causing virus types beyond 16 and 18. This additional efficacy could translate into approximately **11-16% extra protection** against cervical cancer over and above the protection afforded by efficacy against HPV 16 and 18 alone¹.

In India, the same five HPV types are responsible for almost **90% cervical cancer cases**².

"These results amply demonstrate that preventive vaccination is one of the most effective methods of primary prevention of HPV infection, the necessary cause of cervical cancer. In tandem with screening tests, it is perfectly positioned to lend a decisive edge against this deadly cancer. Extending the scope of protection beyond types 16 & 18 will allow prevention of the vast majority of cases of cervical cancer in India. Preventive vaccination against

cervical cancer has now come of age," said Dr. Neerja Bhatla, Additional Professor, Department of Obstetrics and Gynaecology, All India Institute of Medical Sciences.

While sharing the results of the second study- a Comparative trial between Cervarix™ and Gardasil®- **Dr. Shailesh Mehta**, Medical Director, Clinical R&D, Medical Affairs Biologicals – South Asia, GlaxoSmithKline Pharmaceuticals Limited, said, "The comparative trial results presented first at the 25th International Papillomavirus conference demonstrated that GSK's vaccine generates significant and higher immune response³. In women aged 18-45 years who received all 3 doses, neutralizing antibody levels were over two times higher for HPV 16 and over six times higher for HPV 18 than those generated by Gardasil®³."

Findings of the third pivotal study- a long term follow up study- showed that GSK's Cervarix™ provided **high and sustained antibody levels** against HPV 16 and HPV 18 through the **7.3 years of follow up** after vaccination. This is the **longest follow up** reported to date for any licensed HPV vaccine⁴.

"Also, the World Health Organization (WHO) has recently awarded prequalification to Cervarix®⁵. The WHO prequalification is necessary for UN agencies and the GAVI Alliance to purchase the vaccine in partnership with developing countries and will help speed access to Cervarix® globally. Vaccines is one of our key focus areas. And Cervarix™ is important because preventing cervical cancer is a public health priority in both developed and developing countries," **added Dr. Hasit Joshipura**.

GlaxoSmithKline Biologicals – GSK Biologicals, GlaxoSmithKline's vaccines business, is one of the world's leading vaccine companies and a leader in innovation. The company is active in the fields of vaccine research, development and production with over 30 vaccines approved for marketing and 20 more in development. Headquartered in Belgium, GSK Biologicals has 13 manufacturing sites strategically positioned around the globe. In 2008 GSK Biologicals distributed **1.1 billion doses of its vaccines to 176 countries** in both the developed and the developing world – an average of **3 million doses a day**.

Through its accomplished and dedicated workforce, GSK Biologicals applies its expertise to discover innovative vaccines that contribute to the health and well-being of people of all generations around the world.

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.

For further information please visit **www.gsk.com** OR **www.gsk-india.com**.

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