

MSD India launches GARDASIL - India's first Human Papillomavirus (HPV) Vaccine to help prevent Cervical Cancer

Cervical Cancer: the No. 1 cancer among Indian Women; GARDASIL, can help prevent Cervical Cancer and other HPV related diseases among Indian Women.

New Delhi, Delhi, October 14, 2008 /[India PRwire](#)/ -- MSD Pharmaceuticals (India), the local affiliate of Merck & Co., Inc., Whitehouse Station, N.J., USA today announced the launch of GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16 & 18) Vaccine], India's first vaccine to help prevent Cervical Cancer caused by the HPV types contained in the vaccine.

GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16 & 18) Vaccine] is the only vaccine that helps protect against 4 types (Types 6, 11, 16, 18) of HPV. The vaccine helps prevent diseases such as cervical cancer; abnormal and precancerous cervical lesions, vaginal lesions, vulvar lesions; and genital warts, caused by these types of HPV. **GARDASIL®** is recommended to be given to females aged between 9 to 26 years. GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16 & 18) Vaccine] is also the only USFDA approved vaccine to help prevent against cervical cancer and other diseases caused by HPV types contained in the vaccine.

Cervical Cancer, or cancer of the uterine cervix, is a serious disease that can be life-threatening. This disease is caused by certain high-risk HPV types that can cause the cells in the lining of the cervix to change from normal to precancerous lesions. If these precancerous lesions are not diagnosed early and treated, they may turn cancerous after a few years. Cervical Cancer takes the lives of 8 women in India every hour. It is the commonest cause of cancer deaths among Indian women, and the second most common cause of cancer deaths among women worldwide. Every year, almost 74,000 women die due to Cervical Cancer in India, which is more than one fourth of the world deaths due to Cervical Cancer. Woman in India have a 2.5% life time risk to get Cervical Cancer, which is double the risk as compared to the data worldwide (1.3%).

Announcing the launch, **Dr. Naveen A. Rao, Managing Director**, MSD India, said, "MSD India is committed to addressing diseases of high burden in India. With the launch of GARDASIL®, we have initiated the war against Cervical Cancer, the number one cause of mortality amongst Indian women due to cancer. In line with our commitment to putting patients first, MSD India will work with partners and communities to enhance awareness for the disease and access for the vaccine."

Dr. Neerja Bhatla from the All India Institute of Medical Sciences (AIIMS, New Delhi) said, that "Placebo controlled, double blind, randomized, multicentric studies done in more than 20,000 females across 5 continents show that in women who did not have evidence of exposure to HPV types contained in the vaccine GARDASIL® provides 98% protection against cervical pre-cancers caused by HPV types 16 & 18, which are responsible for 70% of all Cervical Cancer cases worldwide. Similarly, in large placebo controlled, double blind, randomized, multicentric studies, the vaccine has also been proven to be 99% effective in the prevention of genital warts caused by HPV types 6 and 11, which are responsible for 90% of all genital warts cases worldwide. In India the number of cases is increasing every year. This is a very promising breakthrough but women must remember that they still need to visit their doctors for regular screening for cervical and other cancers" she added.

Also present at the launch, **Dr. Y. K. Amdekar**, from Jaslok & Breach Candy Hospital, Mumbai (who is also Ex president of Indian Academy of Pediatrics) said, " This quadrivalent HPV vaccine, has demonstrated efficacy in a number of diseases including Cervical Cancer and Genital warts. HPV vaccination is now unequivocally recommended by the IAP Committee of Immunization (COI) for females over the age of ten. This decision is based on expected high impact on public health in future as it will help prevent mortality due to cervical cancer in women in their prime age and keep families united and safe. We will be counseling parents about the risks of cervical cancer and the role of HPV while recommending the vaccination"

According to the Indian Academy of Pediatrics Committee of Immunization (IAPCOI) 2008 recommendations: "This vaccine has a favorable tolerability profile and the IAP-COI recommends offering HPV vaccine to all females as per label. The recommended age for initiation of vaccination is 10-12 years and catch up vaccination is permitted up to the age of 26 years. It is recommended to be given in three doses at 0, 2 and 6 months."

Notes to Editor

About Cervical Cancer

Cervical Cancer is the cancer of the cervix (the lower part of the uterus that connects to the vagina) which is caused by a commonly found virus called human papillomavirus or HPV. Cervical cancer develops when abnormal cells in the lining of the cervix begin to multiply out of control in response to persistent infection with high risk HPV types.

In India, Cervical cancer ranks as the no. 1 most common cancer among women well ahead of breast cancer. More than 365 million Indian women (>15 yrs of age) today are at a risk of Cervical Cancer. Annually more than 1.3 lac (132082) women are diagnosed to have Cervical Cancer in India and that amounts to more than 25% of the world's burden of disease.

Prevention of Cervical cancer requires regular screening and vaccination. Many countries, including the US, Canada, Australia and several European Union member states, already recommend routine HPV vaccination for pre-adolescent girls, usually coupled with catch-up programs for adolescent girls and young women. Several of these countries, including the US, Australia, Germany, France, Sweden and Italy, have started publicly-funded vaccination programs.

About GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16 & 18) Vaccine]

It is a quadrivalent vaccine given as an intramuscular injection, in a total of 3 doses spread over 6 months.

GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16 & 18) Vaccine] is a vaccine indicated in girls and women 9-26 yrs of age for the prevention of the following diseases caused by Human Papillomavirus (HPV) types 6, 11, 16, and 18:

- . Cervical cancer
- . Genital warts (condyloma acuminata) And the following precancerous or dysplastic lesions:
 - . Cervical Intraepithelial Lesion (CIN 1) grade 1
 - . Cervical adenocarcinoma in situ (AIS)
 - . Cervical intraepithelial neoplasia (CIN 2,3) grade 2 and 3
 - . Vulvar intraepithelial neoplasia (VIN 2,3) grade 2 and 3
 - . Vaginal intraepithelial neoplasia (VaIN 2,3) grade 2 and 3

About Merck & Co., Inc. and Merck Sharp & Dohme

Merck & Co., Inc., Whitehouse Station, N.J., USA, which operates in many countries as Merck Sharp & Dohme (MSD), is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck & Co., Inc. discovers, develops, manufactures and markets vaccines and medicines in more than 20 therapeutic categories. The company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck & Co., Inc. medicines but help deliver them to the people who need them. Merck & Co., Inc. also publishes unbiased health information as a not-for-profit service.

About MSD India

MSD Pharmaceuticals Private Limited (MSD India) is a wholly owned Indian subsidiary of Merck & Co., Inc. MSD India was incorporated in India in 2005. Since then the company has moved quickly in laying the foundation for a

successful business in India, one which is differentiated by its focus on putting patients first and bringing first in class and best in class products which are relevant to India. MSD India has presence in four therapeutic areas, namely, critical care, cardiovascular diseases, metabolics and vaccines.

In addition to setting up a sales and marketing structure to market its best in class products in India, MSD is also coordinating research projects with clinical investigators in India's leading hospitals and universities. MSD India is collaborating with the Indian Council of Medical Research, as a public-private partnership to bring Cervical Cancer vaccine to the Indian public sector at an affordable price. MSD Pharmaceuticals currently employs 650 professionals in India, a number which is growing rapidly.

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