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To the Business & Human Rights Resource Centre:

Thank you for providing us with the opportunity to address the press release "Women's Organizations Oppose HPV Vaccines Against Cervical Cancer" and provide accurate information about our approach and vaccine.

As access and equity are key tenets of human rights, and with the imperative to ensure that efforts to advance women's health are afforded the important priority they deserve, we believe that we must work to ensure access to our life-saving human papillomavirus (HPV) vaccine, GARDASIL[®] [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant], and focus special attention on efforts to ensure that it reaches young women living in low income countries where the burden of cervical cancer is greatest.

Around the world, approximately 500,000 women develop cervical cancer, and more than 250,000 die from the disease each year. In India alone, more than 130,000 wives, mothers, sisters and daughters are diagnosed with cervical cancer every year, accounting for one out of four of all cases diagnosed globally. Indeed, cervical cancer is the most common cancer among women in India and every year 74,000 women die as a result. Given the global, local, familial and personal impact of cervical cancer, we agree with many global health leaders who have advocated the belief that working to ensure access to the latest technologies to prevent, detect and treat cervical cancer is both a critically important public health and human rights goal. Expanding access to vaccines is particularly critical to the health and economies of developing countries. As such, MSD has supported a comprehensive approach to helping reduce the burden of cervical cancer in India and around the world by supporting education, vaccination, screening and treatment initiatives.

Given that diseases caused by HPV represent a significant global health burden MSD is proud to have researched and developed, and to now produce, GARDASIL, the world's first HPV cancer vaccine, a vaccine that can help prevent cervical, vulvar and vaginal cancers and genital warts caused by HPV types 6, 11, 16 and 18. GARDASIL has also demonstrated some protection against 10 additional cervical cancer causing HPV types.

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GARDASIL is the result of over 10 years of research and development. As part of the rigorous scientific vaccine clinical development program, clinical trials evaluating the efficacy and safety of the vaccine have included more than 25,000 women from 33 countries from around the world.

In a phase III clinical trial of the safety and efficacy of GARDASIL, the vaccine was 98% effective in preventing the globally accepted immediate and obligate precursors of cervical cancer, carcinoma in situ 2/3 (CIN 2/3), in women 16-26 years of age naïve to the relevant HPV type. As HPV 16 and 18 cause approximately 70% of cases of cervical cancer, GARDASIL is expected to have a significant impact in decreasing rates of cervical cancer in immunized individuals. The compelling clinical data of our HPV vaccine have led to regulatory approvals for GARDASIL in over 110 countries around the world, including India and in 2009 became the first cervical cancer vaccine to receive World Health Organization (WHO) pre-qualification (www.who.int/immunization/documents/HPV_position_paper_summary.pdf). WHO pre-qualification aims to ensure that vaccines meet WHO standards of quality, safety and efficacy. The WHO Strategic Advisory Group of Experts (SAGE) found that the efficacy and safety of available HPV vaccines, as well as the importance of decreasing the global burden of cervical cancer, supports efforts that ensure the global availability of these vaccines. Furthermore, when HPV vaccination is included as part of comprehensive cervical cancer prevention strategies that include HPV disease screening programs, progress in decreasing cervical cancer diagnoses and deaths will be further enhanced.

In India, the Indian Academy of Pediatrics Committee on Immunization (IAPCOI) stated that HPV vaccine is of public health importance and recommends giving the vaccine prior to sexual debut (<http://www.iapcoi.com/hpv.htm>). In 2006 the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommended that girls and women 11 to 26 years old be vaccinated with an HPV vaccine such as GARDASIL (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm?s_cid=rr5602a1_e). As the vaccine is routinely recommended for young women in the United States and many other wealthy countries, we would consider it unacceptable not to work with global health partners to ensure that the vaccine is also available in more resource-constrained countries, such as India, where the burden of cervical cancer is greatest.

While it is difficult to determine the exact number of doses administered, since its launch in 2006 more than 55 million doses of GARDASIL have been distributed worldwide as part of the global fight against HPV diseases.

In addition to the work done in our clinical trials, MSD has established a robust surveillance program to monitor the long-term safety, efficacy and duration of protection of people who are vaccinated with GARDASIL. MSD monitors vaccine safety by conducting analyses of adverse events reported to MSD, and we share these adverse event analyses with regulatory and medical authorities around the world. We are also actively engaged in studies to determine the duration of protection induced by the recommended three dose vaccination series for GARDASIL. Preliminary studies conducted to date have encouragingly demonstrated that there is no waning of protective immunity at five years following vaccination. MSD is conducting long-term follow up studies to confirm whether immunity to HPV disease is long lasting.

While no vaccine or medicine is completely without risk, leading international health organizations throughout the world including the Drug Controller General of India, the WHO, the CDC, Health Canada, the European Medicines Agency (EMA), the Australia Therapeutic Goods Administration (TGA), among others, have reviewed all of the safety information available to them about GARDASIL and continue to recommend its use.

As recently as August of 2009, the U.S Food and Drug Administration (FDA) and CDC have stated that they "continue to find that GARDASIL is a safe and effective vaccine and its benefits continue to outweigh its risks." In addition, the WHO's Global Advisory Committee on Vaccine Safety reviewed safety data for GARDASIL in December of 2008 and concluded that there have not been any reports that have "raised sufficient concern to change previous advice given" by the committee. These statements can be found at the following links:

www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm179549.htm
http://www.who.int/vaccine_safety/Dec_2008/en/index.html

Nothing is more important to MSD than the safety of our medicines and vaccines and we are confident in the safety profile of GARDASIL. Our children, our parents, our spouses and we, ourselves, are vaccinated with the same vaccines that we distribute to the public every day. MSD knows that people around the world make choices about the medicines and vaccines used by their families, too. That is why we remain committed to the global fight against cervical cancer.

MSD pursues its efforts to enable global access to GARDASIL through extensive research efforts to demonstrate the efficacy and safety of the vaccine, through programs exploring novel approaches to provide access to the vaccine in resource-constrained countries (such as the GARDASIL Access Program www.gardasilaccessprogram.org), through tiered pricing policies that provide the vaccine at dramatically lower prices in the world's poorest countries, through partnerships to enable global availability and through providing vaccine at no cost to partners (such as PATH – www.path.org and the International Agency for Research on Cancer [IARC] - www.iarc.fr) who are exploring innovative approaches to effectively provide the vaccine to young women living in low income communities. We are pleased to be able to facilitate the work of the very capable, ethical and experienced partner organizations such as these who share our belief that all women should be able to benefit from newly available strategies for the prevention of cervical cancer.

As efforts advance to enable live-saving new health technologies to reach those living in the developing world or impoverished communities in middle income countries, it is essential that accurate information be available to inform policy makers and the public about the effectiveness and safety of new medical innovations.

MSD is in the business of preserving and improving human life. We firmly believe that it is MSD's responsibility to conduct our research, development and commercialization efforts according to the highest ethical standards and to be very transparent with respect to communicating the information we generate. We appreciate the opportunity to provide information about GARDASIL to all parties who are interested in this important new vaccine, and hope that the information about the vaccine is communicated widely and accurately to help advance efforts to limit the tremendous global burden of cervical cancer.

Best regards,



Dr. Swashraya Shah
Medical Director
MSD Pharmaceuticals Pvt. Ltd.



Dr. Mark Feinberg
Vice President
Medical Affairs and Policy
Merck Vaccines

Important Information About Gardasil

GARDASIL is a vaccine indicated for the prevention of cervical, vulvar, and vaginal cancers; precancerous or dysplastic lesions; genital warts; and infection caused by HPV Types 6, 11, 16, and 18.

GARDASIL is recommended for children and adolescents 9 through 17 years of age and women 18 through 45 years of age.

GARDASIL should be administered in 3 separate intramuscular injections in the deltoid region of the upper arm or in the higher anterolateral area of the thigh over a 6-month period with the first dose at an elected date, the second dose 2 months after the first dose, and the third dose 6 months after the first dose.

Syncope, sometimes associated with falling, has occurred after vaccination with GARDASIL. Therefore, vaccinees should be carefully observed for approximately 15 minutes after administration of GARDASIL.

Select Safety Information

GARDASIL is contraindicated in individuals who are hypersensitive to the active substances or to any of the excipients of the vaccine. Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL should not receive further doses of GARDASIL.

Pregnancy should be avoided during the vaccination regimen for GARDASIL.

Vaccination with GARDASIL may not result in protection in all vaccine recipients.

This vaccine is not intended to be used for treatment of active genital warts; cervical, vulvar, or vaginal cancers; cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), or vaginal intraepithelial neoplasia (VaIN).

This vaccine will not protect against diseases that are not caused by HPV.

The most common adverse reaction was headache. The vaccine-related adverse experiences that were observed among recipients of GARDASIL at a frequency of at least 1.0% and greater than placebo were pain at the injection site, swelling, erythema, pruritus, bruising, pain in extremity, fever, nausea, and dizziness.

Syncope, sometimes accompanied by tonic-clonic movements, has been reported.

Before administering GARDASIL, please consult the full Prescribing Information.