GARDASIL® 9: 2-dose schedule approved in Europe

The European Commission granted marketing authorization for a 2-dose schedule in 9-14 year old girls and boys for GARDASIL®9, the 9-valent HPV vaccine

Lyon, France – April 7 2016 - Sanofi Pasteur MSD announced today that the European Commission has approved a two-dose schedule for adolescent girls and boys aged 9 to 14 for GARDASIL®9, its 9-valent Human Papillomavirus (HPV) vaccine, for use in the 31 countries regulated by the European Medicines Agency (EMA). This new schedule brings the label for GARDASIL®9 in line with recommendations in several European countries that opted for 2-dose schedules in routine vaccination of adolescents in this age group, thereby enabling GARDASIL®9 to be considered in national vaccination programmes.

GARDASIL®9 has been licensed in Europe since June 2015 according to a 3-dose schedule for active immunisation of individuals from the age of 9 years against cervical, vulvar, vaginal and anal cancers causally related to vaccine HPV types, and genital warts causally related to vaccine HPV types. It has been available in the United States since early 2015, with 7 million doses now distributed.

GARDASIL®9 is the only HPV vaccine to protect from diseases caused by 9 HPV types. In Europe these 9 types are responsible for approximately 90% of cervical cancers, 85-90 % of HPV-related vulvar cancers, 80-85% of HPV-related vaginal cancers, 90-95% of HPV-related anal cancer, and 90% of genital warts.

"*The final approval of the 2-dose schedule for Gardasil 9 by the EU Commission is great news to improve HPV vaccination programmes across Europe for the benefit of all adolescent girls and boys*, said David Khougazian, Chief Executive Officer at Sanofi Pasteur MSD. "*We stand ready to engage with National and local Health Authorities to make Gardasil 9 immediately available in order to set the state-of-the-art HPV immunization programmes in Europe*", he concluded.

Human papillomavirus-related cancers are preventable cancers against which we can readily make progress. SPMSD is working with national authorities to make GARDASIL®9 available throughout Europe, with the first launch based on this 2-dose schedule expected in Germany in the coming weeks. Until GARDASIL®9 is available, it is important to maintain effective HPV vaccination programmes with existing vaccines to ensure high vaccination coverage and protection of the populations against the cancers and diseases caused by HPV 16, 18, 6 and 11.

About GARDASIL® 9

GARDASIL® 9, manufactured by Merck, is the first and only nonavalent HPV vaccine helping to protect females and males against genital diseases and cancers caused by 9 human papillomavirus types (6, 11, 16, 18, 31, 33, 45, 52, 58) causing approximately 90% of cervical cancer cases and approximately 80% of high-grade cervical lesions (cervical precancers, defined as CIN 2, CIN 3 and AIS) worldwide.

Seven HPV types also cause 85-90% of HPV-related vulvar cancers, 80-85% of HPV-related vaginal cancers, and 90-95% of HPV-related anal cancers. HPV types 6 and 11 cause approximately 90% of genital warts cases.

About the 2-dose variation

The European license application is supported by the results of a clinical trial performed in about 1,200 girls and boys aged 9 to 14 years old, compared to a group of 300 young women 16 to 26 years old, the age group in which the efficacy of GARDASIL® 9 was demonstrated. The study successfully showed the non-inferiority of the anti-HPV immune responses for all 9 types in girls and boys 9-14 years of age who received 2 doses either in a 0, 6 months schedule or a 0, 12 months schedule, compared to young women 16-26 years of age who received 3 doses in a 0, 2, 6 months schedule.

About GARDASIL®

Gardasil®, manufactured by Merck, is the only quadrivalent HPV vaccine helping to protect people from genital diseases and cancers caused by the human papillomavirus types 6, 11, 16 and 18: cervical cancer, anal cancer, precancerous lesions of the cervix (CIN2/3), precancerous lesions of the anus (AIN 2/3), precancerous lesions of the vulva (VIN2/3) and vaginal (VaIN2/3) and genital warts (condyloma acuminata).

Data published since Gardasil® came on the market 10 years ago have confirmed the positive impact of this vaccine on the prevention of cervical precancerous lesions and genital diseases caused by human papillomavirus types 6, 11, 16 and 18.

Launched nearly 10 years ago in 2006, Gardasil is Western Europe's leading HPV vaccine with over 33 million doses distributed and approximately 205 million doses distributed worldwide to date.

About Sanofi Pasteur MSD http://www.spmsd.com (http://www.spmsd.com)

Sanofi Pasteur MSD is a European joint venture formed between Sanofi Pasteur (the vaccine division of Sanofi) and Merck (known as MSD outside the United States and Canada). Combining innovation and expertise, Sanofi Pasteur MSD is the only European pharmaceutical company dedicated exclusively to the distribution of vaccines. Sanofi Pasteur MSD makes use of the combined expertise resulting from Sanofi Pasteur and Merck’s research to focus on the development of new vaccines in Europe in order to produce the most effective, most acceptable and better tolerated vaccines.