Sanofi Pasteur Announces the Registration of Menactra® by the Health Council for Arab Countries in the Gulf

-The approval paves the way for the launch of the meningitis vaccine in 7 Arab Gulf States-

Lyon, France – June 22, 2010 - Sanofi Pasteur, the vaccines division of sanofi-aventis Group, announced today that it has received the registration certificate for its meningococcal quadrivalent (A,C,Y, and W-135) conjugate vaccine, Menactra®, by the Executive Board of the Health Ministers’ Council for Gulf Cooperation Council (GCC) States.

The Health Ministers’ Council for Gulf Cooperation Council (GCC) States—previously known as The Health Ministers’ Council of the Arab Countries in the Gulf—was created in 1976 and includes the following seven Arab Gulf states: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates, and Yemen. According to the registration by the Health Ministers’ Council for GCC states, Sanofi Pasteur is now able to contact the member countries in GCC in order to complete their administrative procedures for local pricing of Menactra vaccine in each of the GCC countries.

“This registration approval by the GCC paves the way for Menactra vaccine to be used—for the first time—outside of North America to protect people from this devastating disease,” explained Wayne Pisano, president and CEO, Sanofi Pasteur. “We are looking forward to providing our meningococcal quadrivalent conjugate vaccine to the GCC Countries and- eventually, the rest of the world- following the successful introduction of the product in the U.S. and Canada.”

About Invasive Meningococcal Disease
Invasive Meningococcal Disease (IMD), which includes meningitis, is a serious bacterial infection. Although uncommon in some countries and more frequent in others, IMD can lead to meningitis (swelling of the brain or spinal cord) or meningococcemia (blood infection).1,2,3,4 The disease can be spread through common everyday activities, such as sharing eating utensils and drinking glasses, living in close quarters like dormitories or summer camps, and kissing.4,5,6 Meningococcal disease can be hard to recognize, especially in its early stages, because symptoms are similar to those of more common viral illnesses.4 Unlike more common illnesses, the disease can progress quickly and may cause death or disability in just a single day.5,7
The Islamic Hajj pilgrimage to Mecca, Kingdom of Saudi Arabia (KSA) has historically been associated with outbreaks of *Neisseria meningitidis* serogroup A. The main means of prevention against IMD was the bivalent serogroup A/C polysaccharide vaccine. During the Hajj pilgrimages of 2000 and 2001, there was an epidemiological shift from serogroup A to serogroup W-135 disease, with subsequent increases in younger age groups. This prompted the Ministry of Health to introduce quadrivalent (A,C,Y, and W-135) polysaccharide vaccines. These interventions have quelled IMD since 2002. Historically, conjugate vaccines have been shown to induce immune responses that generally last longer and can be better boosted than those following polysaccharide vaccination. Clinical trials of Menactra® among Saudi Arabian children and adolescents have been completed and the findings from these studies were presented at the European Meningococcal Disease Society meeting in June 2009.

**About Menactra®**

Menactra® (Meningococcal [Groups A, C, Y and W-135] Polysaccharide Diphtheria Toxoid Conjugate Vaccine) is the only licensed conjugate vaccine for persons two through 55 years of age for active immunization against IMD caused by *N meningitidis* serogroups A, C, Y, and W-135. Since it was first licensed in the U.S. by the Food & Drug Administration (FDA) in 2005, more than 30 million doses of Menactra vaccine have been distributed in that country.

A vaccine industry leader, Sanofi Pasteur has been a pioneer in meningococcal vaccine development with over three decades of experience. The company first introduced meningococcal vaccines that offered protection against serogroups A and C in the early 1970s. In 1981, Menomune®-A/C/Y/W-135 (Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined) became the first meningococcal vaccine available to protect against IMD caused by four of the five most common serogroups (A, C, Y and W-135).

In 2005, Menactra® was granted FDA licensure and became the first and only quadrivalent meningococcal conjugate vaccine available in the U.S. for those 11 through 55 years of age. Two years later the age indication was extended down to the age of two years. In 2007, Menactra® vaccine was also licensed for those two through 55 years of age in Canada.

Side effects to Menactra® include those common to most vaccines: headache, fatigue, injection-site pain, redness, and swelling. Other side effects may occur. Vaccination should be avoided by persons with known hypersensitivity (severe allergic reaction) to any ingredient of the vaccine, including latex (which is used in the vial stopper), or by any persons previously diagnosed with Guillain-Barré syndrome. Vaccination with Menactra® may not protect all individuals.

For more information about Menactra®, please visit: [www.menactra.com](http://www.menactra.com)

**About sanofi-aventis**

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). For more information, please visit: [www.sanofi-aventis.com](http://www.sanofi-aventis.com)
Sanofi Pasteur, the vaccines division of sanofi-aventis Group, provided more than 1.6 billion doses of vaccine in 2009, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur offers the broadest range of vaccines protecting against 20 infectious diseases. The company’s heritage, to create vaccines that protect life, dates back more than a century. Sanofi Pasteur is the largest company entirely dedicated to vaccines. Every day, the company invests more than EUR 1 million in research and development. For more information, please visit: www.sanofipasteur.com or www.sanofipasteur.us

References


Forward Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential and statements regarding future performance. Forward-looking statements are generally identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans” and similar expressions. Although sanofi-aventis’ management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group’s ability to benefit from external growth opportunities as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in sanofi-aventis’ annual report on Form 20-F for the year ended December 31, 2009. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

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