

Swiftwater, PA, October 19, 2007

## **Sanofi Pasteur receives FDA approval of meningococcal vaccine for children**

### **Menactra<sup>®</sup> meningococcal conjugate vaccine approved for use in children 2 years through 10 years of age**

Sanofi Pasteur, the vaccines division of sanofi-aventis Group, announced today that the U.S. Food and Drug Administration (FDA) has granted licensure to expand the indication for its meningococcal conjugate vaccine, Menactra<sup>®</sup> (Meningococcal [Groups A, C, Y and W-135] Polysaccharide Diphtheria Toxoid Conjugate Vaccine), to include children 2 years through 10 years of age.

Menactra<sup>®</sup> vaccine is the first and only quadrivalent conjugate vaccine licensed in the U.S. for the prevention of meningococcal disease. The vaccine first received FDA licensure in 2005 for immunization of adolescents and adults 11 years through 55 years of age. Menactra vaccine offers protection against four of the five most common serogroups of the bacterium that cause meningococcal infection, *Neisseria meningitidis* serogroups A, C, Y and W-135. No vaccine is available in the United States for protection against infection from serogroup B.

*"We have been waiting for this expansion of use of Menactra<sup>®</sup> to younger children, since they too are at risk and may benefit from the vaccine. Meningococcal disease is serious and no healthy child should have to risk permanent disability, or even death, from this vaccine-preventable disease. About half of the cases in children 2 years through 5 years, and two-thirds in those 6 years through 11 years can potentially be prevented through vaccination in the United States"* said Michael Pichichero, MD, professor of microbiology/immunology, pediatrics and medicine, University of Rochester Medical Center.

#### **Clinical Studies**

The FDA's decision to license Menactra<sup>®</sup> vaccine for children 2 years through 10 years of age was based on safety and immunogenicity data from two large clinical studies. Both studies were randomized, multi-center, active-controlled, modified double-blind clinical studies of children 2 years through 10 years of age comparing the safety and immunogenicity of Menactra<sup>®</sup> vaccine to Menomune<sup>®</sup>-A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined. A third multi-center, open-label study of children 4 years through 6 years of age evaluated the antibody memory response to the vaccine in children who had been vaccinated previously with Menactra<sup>®</sup> vaccine approximately two years earlier.



Data from the studies indicated that the vaccine was safe and immunogenic for children 2 years through 10 years of age. Immune responses were significantly greater for all four serogroups in those who received Menactra<sup>®</sup> vaccine than those who received Menomune-A/C/Y/W-135 vaccine. In addition, compared to Menomune-A/C/Y/W-135 vaccine, Menactra<sup>®</sup> vaccine resulted in longer-term persistence of bactericidal antibody, production of high avidity antibody, and the establishment of immune memory. No clinically significant adverse events were identified after a six-month controlled follow-up. In the studies, immediate reactions were uncommon and consisted primarily of local redness at or near the injection site. Reactions were reported for the most part as mild and of short duration. Solicited systemic reactions were similar among the study groups and were described for the most part as mild, reversible and of short duration. The most common solicited complaints among children 2 years through 10 years of age were injection site pain and irritability.

### **Immunization Recommendations**

Since its introduction in 2005 there has been strong acceptance by health-care providers and consumers for Menactra<sup>®</sup> vaccine. This was evident by the increased uptake following new vaccination recommendations issued by the Centers for Disease Control and Prevention (CDC) in June 2007 calling for meningococcal immunization for all adolescents 11 years through 18 years of age.

Sanofi Pasteur will continue to work closely with the CDC's Advisory Committee on Immunization Practices regarding recommendations for children younger than 11 years of age, now that FDA has licensed Menactra<sup>®</sup> vaccine for use in children 2 years through 10 years of age.

For more information about Menactra<sup>®</sup> vaccine, please visit [www.sanofipasteur.us](http://www.sanofipasteur.us). Immunization providers can order Menactra vaccine by visiting [www.vaccineshoppe.com](http://www.vaccineshoppe.com) or calling 1-800-VACCINE (1-800-822-2463).

### **About Meningococcal Disease**

Meningococcal disease is a rare but serious bacterial infection that strikes between 1,400 and 2,800 Americans every year, causing meningitis or sepsis in the majority of cases. Approximately 10 percent of individuals who contract meningococcal disease will die. Of those who survive, up to one in five suffer permanent disabilities such as hearing loss, neurological damage and limb amputations. Meningococcal disease often begins with symptoms that can be mistaken for common viral illnesses, such as the flu. But unlike more common infections, meningococcal disease can progress very rapidly and kill an otherwise healthy young person in 48 hours or less.

### **Indication**

Menactra<sup>®</sup> vaccine is indicated for active immunization against invasive meningococcal disease caused by *N. meningitidis* serogroups A, C, Y, and W-135 in people 2 years through 55 years of age. Menactra vaccine will not stimulate protection against infection, caused by *N. meningitidis* other than serogroups A, C, Y, and W-135.

### **Safety Information**

There are risks associated with all vaccines. The most common local and systemic adverse reactions to Menactra vaccine include injection site pain, redness, and induration; headache, fatigue, and malaise. Other adverse reactions may occur. Menactra vaccine is contraindicated in persons with known hypersensitivity to any component of the vaccine or to latex, which is used in the vial stopper. Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of Menactra vaccine. Persons previously diagnosed with GBS should not receive Menactra<sup>®</sup> vaccine. As with any vaccine, vaccination with Menactra<sup>®</sup> vaccine may not protect 100 percent of individuals.

### **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).

Sanofi Pasteur, the vaccines division of sanofi-aventis Group, provided more than a billion doses of vaccine in 2006, 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 EUR1 million in research and development. For more information, please visit: [www.sanofipasteur.com](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://www.sanofipasteur.us)

### **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 financial projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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 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, 2006. 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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