



## Menomune<sup>®</sup> Is the First Quadrivalent Meningococcal Vaccine Prequalified by the WHO

*- Prequalification Makes the Vaccine Eligible for Purchase by United Nations Agencies -*

**Lyon, France - September 3, 2013** - Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), announced today that one of its quadrivalent vaccines to prevent invasive meningococcal disease has been prequalified by the World Health Organization (WHO). The prequalification procedure accepts Menomune<sup>®</sup> vaccine for purchase by United Nations Agencies. The UNICEF supply division has been notified of Menomune vaccine's acceptance by the WHO.

The purpose of the United Nations prequalification assessment is to provide assurance that candidate vaccines meet WHO recommendations on quality, safety and efficacy, including compliance with WHO's recommended standards for good manufacturing practice (GMP) and good clinical practice (GCP). This Menomune vaccine prequalification was performed through a streamlined procedure in which the WHO worked closely with the United States Food and Drug Administration (FDA).

Menomune vaccine is designed for active immunization against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135 for use in persons 2 years of age and older. It is the first quadrivalent meningococcal vaccine pre-qualified by the WHO. The WHO notification to UNICEF states that following the evaluation of consistency of final product characteristics, GMP and quality system audits of the manufacturing facilities, and follow-up of implementation of recommendations made by WHO reviewers during the evaluation, Menomune vaccine has been found acceptable. It is manufactured in Pennsylvania, USA.

*"Sanofi Pasteur's commitment to help protect against meningococcal disease began almost 40 years ago with the introduction of a monovalent vaccine that offered protection against serogroup A and a bivalent vaccine that offered protection against serogroups A and C,"* said Olivier Charmeil, President and Chief Executive Officer, Sanofi Pasteur. *"Our commitment to remaining at the forefront of advancing the prevention of meningococcal disease, worldwide, continues today."*

Menomune – A/C/Y/W-135 vaccine was first licensed by the U.S. FDA in 1981. It is now licensed in 17 countries with more than 22 million doses shipped worldwide since it first became available.

*"The value of a quadrivalent meningococcal vaccine is becoming more and more realized as evidenced by the circulation of the W-135 strain in the western part of the African meningitis belt this past year,"* explained Luc Kuykens, M.D., M.P.H., Sanofi Pasteur's Chief Medical Officer. *"Menomune is a proven vaccine with a 32-year track record of providing broad protection against this serious disease, so we try to keep a stockpile of the vaccine in case of any outbreaks."*

### **About Meningococcal Disease**

Although rare, meningococcal disease can cause meningitis (swelling of the brain or spinal cord) or meningococemia (blood infection). The disease can be spread through common everyday activities, such as sharing eating utensils and drinking glasses, living in close quarters or attending crowded events. Meningococcal disease can be hard to recognize, especially in its early stages, because



symptoms are similar to those of more common viral illnesses. Unlike more common illnesses, the disease can progress quickly and may cause death or disability in just a single day.

## About Menomune Vaccine

### Indication

Menomune-A/C/Y/W-135 vaccine is indicated for active immunization against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135. Menomune-A/C/Y/W-135 vaccine is approved for use in persons 2 years of age and older. Menomune-A/C/Y/W-135 vaccine does not prevent *N. meningitidis* serogroup B disease.

### Safety Information

The most common local and systemic adverse reactions include injection site pain, redness, and swelling; headaches, malaise, and fever. Other adverse reactions may occur. Menomune-A/C/Y/W-135 vaccine is contraindicated in persons with known hypersensitivity to any components of the vaccine (including thimerosal). Vaccination with Menomune-A/C/Y/W-135 vaccine may not protect all individuals.

Before administering Menomune-A/C/Y/W-135 vaccine, please see full Prescribing Information.

## About Sanofi

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Pasteur, the vaccines division of Sanofi, provides more than 1 billion doses of vaccine each year, 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](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 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's 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, 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 product candidates, the absence of guarantee that the product 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, trends in exchange rates and*



*prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2012. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

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## **Contacts:**

### **Global Media Relations**

Alain Bernal  
T. +33-4-37-37-50-38  
[alain.bernal@sanofipasteur.com](mailto:alain.bernal@sanofipasteur.com)  
[www.sanofipasteur.com](http://www.sanofipasteur.com)

### **U.S. Media Relations**

Susan H. Watkins  
T. +1-570-957-2563  
[susan.watkins@sanofipasteur.com](mailto:susan.watkins@sanofipasteur.com)  
[www.sanofipasteur.us](http://www.sanofipasteur.us)

### **Investor Relations**

Sebastien Martel  
T. +33-1-53-77-45-45  
[ir@sanofi.com](mailto:ir@sanofi.com)  
[www.sanofi.com](http://www.sanofi.com)