



Sanofi Pasteur's 6-in-1 Pediatric Vaccine Hexaxim™ Receives Positive Opinion from European Medicines Agency

- EMA scientific opinion opens the door for registration of Hexaxim™ in international markets outside Europe -
- Hexaxim™, the only fully-liquid, ready to use 6-in-1 pediatric vaccine to improve the standard of care of childhood vaccination worldwide -

France, Lyon – June 22, 2012 – Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), announced today that Hexaxim™ (DTaP-IPV-Hib-HepB vaccine) received a positive scientific opinion from the European Medicines Agency (EMA), as part of a procedure designed to evaluate medicinal products intended for markets outside the European Union. This is the first time the EMA gives a positive scientific opinion to a vaccine following that procedure. Hexaxim™ is the only fully liquid, ready to use 6-in-1 vaccine to protect infants against diphtheria, tetanus, pertussis (whooping cough), Hepatitis B, poliomyelitis and invasive infections caused by *Haemophilus influenzae* type b.

“Our goal is to provide access to children throughout the world to the same standard of care for childhood immunization. Availability of Hexaxim™ ready to use 6-in-1 pediatric vaccine will raise the standard of care of vaccination for millions of children,” said Olivier Charmeil, President and CEO of Sanofi Pasteur. *“Upon licensure we intend to introduce Hexaxim™ in countries looking for improved and effective solutions in particular for public immunization programs.”*

The EMA scientific opinion is based on the review of a dossier submitted by Sanofi Pasteur through the “Article 58” procedure. The EMA assessment was conducted with the participation of experts from the World Health Organization (WHO) according to the same quality, safety and efficacy criteria as vaccines authorized for the European Union. Many countries in Latin America, Africa, the Middle East and Asia grant market authorization based on the EMA scientific opinion.

“A 6 in 1 pediatric vaccine reduces the number of vaccination visits for infants. It is more convenient for parents to complete the recommended vaccination schedule and thus better protect their children against 6 major childhood diseases,” said Dr Pio Lopez, Pediatrician, Infectologist, Professor at the Universidad del Valle in Cali and President of the Vaccines Chapter of the Colombian Association of Infectious Diseases (ACIN), and principal investigator for a clinical study of the vaccine in Colombia. *“Hexaxim also includes inactivated poliovirus vaccine which is an important step to ensure communities remain polio-free.”*

Key benefits of Hexaxim™ vaccine:

- Hexaxim™ is a fully liquid, ready to use vaccine; no reconstitution is needed prior to administration which improves convenience for health care professionals. It is available in vial and/or syringe presentations.
- By combining six vaccines into one, Hexaxim™ reduces the number of injections, which improves comfort and vaccination compliance for infants.



- The use of acP (acellular pertussis) antigens and IPV (inactivated poliovirus vaccine), both commonly used in North America and Europe, improves safety and reduces reactogenicity as compared to wcP (whole cell pertussis)-containing vaccines and OPV (oral polio vaccine).

Upon approval, Hexaxim™ would be indicated for primary and booster vaccination of infants from six weeks of age in accordance with official recommendations.

The EMA positive opinion is supported by results of multi-center clinical studies involving approximately 4,000 infants in Argentina, Peru, Mexico, South Africa, and Thailand. Phase III clinical studies comparing Hexaxim™ to licensed combination vaccines demonstrated that Hexaxim™ is safe and induces a robust immune response against the six targeted diseases.

Hexaxim™ complements Sanofi Pasteur's Acxim family of acP-IPV (acellular pertussis vaccine, inactivated poliovirus vaccine) combination vaccines. To date, more than 180 million doses of Sanofi Pasteur's acP-IPV containing vaccines have been distributed in over 100 countries and have been included in the national immunization programs in over 30 countries. Hexaxim combines the same antigens included in the well-established vaccines Tetraxim®/Tetravac® (DTaP-IPV vaccine) and Pentaxim®/ Pentavac® (DTaP-IPV-Hib vaccine), with Sanofi Pasteur's new hepatitis B antigen.

About Sanofi

Sanofi, a global and diversified 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 or 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, 2011. 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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