



European Medicines Agency Recommends Approval of Hexyon/Hexacima 6-in-1 Pediatric Vaccine

- Hexyon/Hexacima will be the only fully liquid, ready-to-use, 6-in-1 pediatric vaccine in Europe -

Lyon, France - February 22, 2013 - Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended market approval for Sanofi Pasteur's 6-in-1 pediatric vaccine Hexyon™/Hexacima™ (DTaP-IPV-Hib-HepB vaccine).

Hexyon™/Hexacima™ 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.

The new vaccine will be commercialized under the brand name Hexyon™ in Western European countries* by Sanofi Pasteur MSD, the joint venture between MSD and Sanofi Pasteur, and under the brand name Hexacima™ in Eastern European countries by Sanofi Pasteur.

"Availability of Hexyon/Hexacima ready-to-use, 6-in-1 pediatric vaccine will raise the standard of care of vaccination for millions of children. It reduces the number of vaccination visits for infants and it is more convenient for parents to complete the recommended vaccination schedule and thus better protect their children against six major childhood diseases," said Olivier Charmeil, President and CEO of Sanofi Pasteur. *"Upon licensure, we intend to introduce Hexyon/Hexacima vaccine in countries that are looking for improved and effective solutions for public immunization programs."*

Key benefits of Hexyon™/Hexacima™ vaccine:

- Hexyon™/Hexacima™ is a fully liquid, ready-to-use vaccine; no reconstitution is needed prior to administration, which improves convenience for healthcare professionals. It is available in vial and pre-filled syringe presentations.
- By combining six vaccines into one, Hexyon™/Hexacima™ 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) improves safety and reduces reactogenicity as compared to wcP (whole cell pertussis)-containing vaccines and OPV (oral polio vaccine).

Upon licensure, Hexyon™/Hexacima™ would be indicated for primary and booster vaccination of infants from six weeks of age in accordance with official recommendations.

The CHMP positive opinion is supported by results of multi-center clinical studies involving approximately 5,000 infants. Phase III clinical studies comparing Hexyon™/Hexacima™ to licensed combination vaccines demonstrated that Hexyon™/Hexacima™ is safe and induces a robust immune response against all six targeted diseases.

Hexyon™/Hexacima™ complements Sanofi Pasteur's product family of acP-IPV (acellular pertussis vaccine, inactivated poliovirus vaccine) combination vaccines. The new 6-in-1 vaccine will be available in international markets under the trade name Hexaxim®. 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. Hexyon™/Hexacima™ 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, rare diseases, consumer healthcare, emerging markets and animal health. 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

* France, Germany, UK, Spain, Italy, Belgium, Netherlands, Austria, Portugal, Switzerland, Norway, Sweden, Denmark, Finland, Ireland, Greece, Iceland, Luxembourg, Liechtenstein

Forward-Looking Statements

This press release contains forward-looking statements. 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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