



Sanofi Pasteur's New Quadrivalent Influenza Vaccine Accepted for Review for European Approval

- The addition of a fourth influenza virus strain to the seasonal trivalent vaccine aims to increase protection against influenza -

Lyon, France - April 11, 2013 - Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), announced today that a decentralized marketing authorization application has been accepted for review in the European Union countries for a quadrivalent (four-strain) formulation of Vaxigrip® Sanofi Pasteur's seasonal inactivated split-virion influenza vaccine produced at its facility in Val de Reuil, France. The file has been accepted for review by France's *Agence nationale de sécurité du médicament et des produits de santé* (ANSM) as the regulatory agency for the "Reference Member State", and by national regulatory agencies from the EU countries.

"The inclusion in the seasonal influenza vaccine of the four influenza viruses anticipated to circulate in the forthcoming season has the potential to reduce the risk of influenza disease and influenza-related complications, specifically hospitalizations and deaths among those, at risk, who contract the disease," said Olivier Charmeil, President and CEO of Sanofi Pasteur.

Annual influenza vaccination is considered to date as the most effective method for preventing seasonal flu and its complications. Vaccination is especially important for people at higher risk of serious influenza complications and for people who live with or care for high risk individuals.

Currently licensed trivalent seasonal influenza vaccines are formulated every year, based on the seasonal recommendations made by the World Health Organization (WHO) and national authorities, and contain inactivated strains that confer protection against three different influenza viruses: two influenza A virus subtypes (H3N2 and H1N1) and one influenza B virus.

Influenza viruses are capable of evading the body's immune system by undergoing continuous genetic variation and may change from season to season. Individuals are susceptible to new strains despite previous infection by other influenza viruses. Additionally, for over a decade, two distinct influenza B families (lineages) have co-circulated with varying prevalence, making it difficult to predict which B-lineage strain will predominate in a country or in a region in seasons to come.

Sanofi Pasteur's new quadrivalent influenza vaccine includes two A strains and two B strains corresponding to both of the B lineages.

The marketing authorization application for the quadrivalent version of Vaxigrip® is intended to be presented in all countries of the world where Vaxigrip® (licensed trivalent vaccine) is currently commercialized. Once approved, the new quadrivalent vaccine will be commercialized in Western European countries* by Sanofi Pasteur MSD (the joint venture between MSD and Sanofi Pasteur), and in other countries (including Eastern Europe) by Sanofi Pasteur.



The current application is for the active immunization of children and adults from 9 years of age for the prevention of influenza disease caused by influenza virus subtypes A and B contained in the vaccine. It is based on a clinical development program that involved more than 3,000 adults aged 18 to 60, seniors aged 60 and over and children/teenagers 9 to 17 years old. Clinical trials evaluated the safety of Sanofi Pasteur's new quadrivalent influenza vaccine and its ability to generate an immune response compared to trivalent vaccines. In parallel, development efforts are underway for a pediatric indication of this new quadrivalent influenza vaccine, for children from 6 months to 9 years of age.

Additionally, Sanofi Pasteur filed, in October 2012, a Supplemental Biologics License Application (sBLA) with the U.S. Food and Drug Administration (FDA) for a quadrivalent formulation of its Fluzone® (Influenza Virus Vaccine) produced at the Sanofi Pasteur facility in Swiftwater, Pa. (USA). The sBLA file has been accepted by the FDA for full review and an action date is anticipated in the second quarter of 2013.

As a world leader in the research, development and manufacturing of influenza vaccines, Sanofi Pasteur is dedicated to saving lives through the development of innovative new influenza vaccines. With the production of more than 200 million doses of seasonal influenza vaccine in 2012, Sanofi Pasteur confirmed its leadership by supplying an estimated 40 percent of the world influenza vaccine market.

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

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, 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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