New Four-Strain Influenza Vaccine, VaxigripTetra™, regulatory dossier from Sanofi Pasteur now approved in Europe

New VaxigripTetra™ vaccine:

- A 4-strain influenza vaccine for people 36 months of age and older,
- Helps protect children, adults and seniors against both influenza B strains (B/Victoria and B/Yamagata),
- Newest addition to the Vaxigrip® family of influenza vaccines.

Lyon, France – June 23, 2016 – Sanofi Pasteur, the vaccines division of Sanofi, announced today that its quadrivalent influenza vaccine VaxigripTetra™ obtained a positive end of procedure from the German Reference Member State Paul Ehrlich Institute, as a conclusion of the European Decentralized Procedure. Marketing Authorizations can now be issued in the Reference Member State (Germany) and each of the Concerned Member States involved in this procedure. VaxigripTetra™ is a four-strain influenza vaccine, containing two A strains (A/H1N1 and A/H3N2) and two B strains (B/Victoria and B/Yamagata), for use in individuals aged 36 months or older. VaxigripTetra™ is the newest addition to the Vaxigrip® family of influenza vaccines.

Currently, the majority of seasonal influenza vaccines are trivalent meaning that they protect against three strains: two A strains and a single B strain (B/Victoria or B/Yamagata). However, two distinct influenza B strains (B/Victoria and B/Yamagata) now co-circulate worldwide in varying and unpredictable proportions\(^1\). In recent years, influenza B viruses represented around 23% of the circulating strains around the world. These proportions can be as high as 90% during some seasons and are therefore an important cause of influenza disease\(^2\). Given this current virological situation with the co-circulation of the two B strains, influenza vaccines need to be adapted and to fit with the current virological situation to ensure broader level of protection. Because trivalent influenza vaccines only contain one B strain, this co-circulation makes the selection of the right strains to be included in the seasonal vaccine very difficult to predict. As an example in Europe in 2015 92%\(^3\) of the documented B influenza cases were caused by the B/Victoria strain not included in the vaccine. Adding the second B strain to VaxigripTetra™ will address the unpredictability issue.

“For over 60 years the expertise of Sanofi Pasteur has been committed to providing new immunization solutions for the prevention of influenza to better protect lives and help healthcare providers meet the specific immunization needs of all types of their patients. This new quadrivalent influenza vaccine, which includes both co-circulating B strains, completes our long line of Vaxigrip® family vaccines dedicated to fighting influenza infections and its complications. Once launched in Europe VaxigripTetra™ will offer broader protection for people from 36 months and older and support our public health ambition to constantly innovate to save lives worldwide” said David Loew, Executive Vice President Sanofi Pasteur.
The World Health Organization includes quadrivalent influenza vaccines in its recommendations, stating “Quadrivalent influenza vaccines that could potentially provide wider protection against influenza B viruses are becoming available and recommendations should not be limited to trivalent vaccine.”

From a public health perspective, using quadrivalent rather than trivalent influenza vaccines could have resulted in a further reduction of up to 1.6 million influenza cases, 37,300 influenza-related hospitalizations and 14,800 influenza-related deaths in the EU over a decade.

Sanofi Pasteur supports influenza immunization policies and is committed to developing vaccine solutions that fit with the influenza epidemiology. VaxigripTetra™ is the newest formulation designed by Sanofi Pasteur, offering a quadrivalent influenza vaccine. VaxigripTetra™ includes two A strains and two B strains to help provide broader protection for all age groups as of 36 months. Sanofi Pasteur intends to progressively switch all its trivalent influenza vaccines to quadrivalent influenza vaccines worldwide.

About the evolution of influenza vaccines
Influenza viruses mutate often and the antigenic and ecological evolution results in the need to adapt the vaccine composition annually to ensure it remains effective. Each winter the strains for the seasonal influenza vaccines are selected from the influenza strains anticipated to circulate in the Northern Hemisphere during the approaching influenza season by WHO. Until 1978, seasonal influenza vaccines contained only two strains (one strain of type A influenza and one strain of type B influenza), when the decision was made to incorporate a second type A influenza strain to help provide protection against both A strains that were co-circulating. Since then, influenza vaccines have been trivalent to help protect against three strains of influenza virus: a type A(H1N1), a type A(H3N2) and one type B. However, since the 2001-2002 season, influenza B viruses have diverged into two antigenically distinct lineages (the Victoria and Yamagata lineages). Both B lineages have co-circulated with varying prevalence by season and region, supporting the need for extended protection with quadrivalent influenza vaccines.

About influenza and vaccination
Influenza is a serious respiratory illness. Each year, 3 million to 5 million cases of severe illness are reported worldwide. Depending on virus virulence during the influenza season, influenza associated-deaths can range from 250,000 to 500,000 people worldwide.

In Europe, in the absence of vaccination, the annual burden related to influenza was estimated at 22 million cases, 3.5 million flu-associated hospitalizations and 171,000 flu-associated deaths. Currently seasonal influenza vaccination prevents on average between 1.6 million and 2.1 million cases of influenza, 45,300 to 65,600 hospitalizations, and 25,200 to 37,200 deaths every year. The World Health Organization recommends vaccination to help prevent influenza for everyone six months of age and older.
About Sanofi
Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and 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 produces a portfolio of high quality vaccines that matches its areas of expertise and meets public-health demand. 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 initiatives 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, 2015. 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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