



sanofi pasteur

The vaccines division of sanofi-aventis Group

FDA Licenses Sanofi Pasteur's New Influenza Vaccine Delivered by Intradermal Microinjection

Fluzone[®] Intradermal (Influenza Virus Vaccine) first to offer an immunization option with 90 percent smaller needle

Lyon, France – May 10, 2011 – Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), announced today the U.S. Food and Drug Administration (FDA) has approved the company's supplemental biologics license application (sBLA) for licensure of Fluzone Intradermal (Influenza Virus Vaccine). Fluzone Intradermal vaccine is indicated for active immunization of adults 18 through 64 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

"The microinjection delivery system utilized in Fluzone Intradermal vaccine provides reliable and easy delivery of the vaccine into the dermal layer of the skin, an attractive site for immunization," said Olivier Charmeil, President and CEO, Sanofi Pasteur. *"Sanofi Pasteur is proud to bring this innovation in influenza vaccine administration to the U.S., offering health-care providers a new tool that may help enhance adult influenza immunization rates."*

The new formulation of Fluzone Intradermal vaccine is the first influenza vaccine licensed in the U.S. that uses a novel microinjection system for intradermal delivery. Fluzone Intradermal vaccine features an ultra-fine needle that is 90 percent shorter than the typical needle used for intramuscular injection of influenza vaccine. Sanofi Pasteur has previously licensed microinjection intradermal influenza vaccines, marketed as Intanza[®] or IDflu[®] vaccines, in more than 40 countries including Australia, Canada and countries in Europe.

Fluzone Intradermal vaccine incorporates a new, easy-to-use, prefilled microinjection system designed to consistently deposit vaccine antigens into the dermal layer of the skin of adults. The dermal layer contains a high concentration of specialized cells known as dendritic cells, which play a key role in generating an immune response. In clinical trials, Fluzone Intradermal vaccine produced an immune response at rates similar to Fluzone vaccine administered intramuscularly.

Typically, adult influenza vaccines are administered into the muscle utilizing a needle 1 inch to 1.5 inches (25 mm to 38 mm) in length. Fluzone Intradermal vaccine features an ultra-fine needle that is 0.06 inches (1.5 mm) in length. Fluzone vaccine contains 15 mcg of hemagglutinin per strain of influenza in a 0.5 mL dose. Fluzone Intradermal vaccine contains 9 mcg of hemagglutinin per strain of influenza in a 0.1 mL dose.

Fluzone Intradermal vaccine will be available to health-care providers in the U.S. for the 2011-2012 influenza season. Health-care providers wishing to reserve vaccine can do so by visiting www.vaccineshoppe.com or by calling 1-800-VACCINE (1-800-822-2463).



Fluzone® Intradermal Vaccine Immunogenicity and Safety

Clinical trials were conducted to evaluate the safety and immunogenicity of Fluzone Intradermal vaccine. Fluzone Intradermal vaccine was licensed based on data from a Phase III clinical trial in 4,276 adults 18 years through 64 years of age (2,855 participants received Fluzone Intradermal vaccine and 1,421 participants received Fluzone vaccine via intramuscular administration). The study, which assessed the safety and immunogenicity of Fluzone Intradermal vaccine in comparison to Fluzone vaccine, was presented in October 2010 at the 48th Annual Meeting of the Infectious Diseases Society of America in Vancouver, British Columbia. In the Phase III trial, Fluzone Intradermal vaccine was found to induce immunologic responses similar to licensed Fluzone vaccine.

Systemic reactogenicity of Fluzone Intradermal vaccine was comparable to that of intramuscular administration of Fluzone vaccine in the study. Intradermal microinjection deposits influenza vaccine near the surface of the skin; therefore, local reactions are more easily visible. The most common solicited injection-site reactions reported in participants given the intradermal vaccine were erythema (redness) (>75%), swelling (>50%), induration (hardness) (>50%), pain (>50%) and pruritus (itching) (>40%). The injection-site and systemic reactions with intradermal administration were transient, resolving in three to seven days without sequelae. The injection-site reactions were more frequent with participants given the intradermal vaccine compared to the intramuscular vaccine, with the exception of pain, which was similar.

About Influenza

Influenza is a serious respiratory illness that is easily spread and can lead to severe complications, even death. Each year in the U.S., 5 to 20 percent of the population gets the flu and an estimated 226,000 people are hospitalized from flu-related complications. Flu seasons are unpredictable and can be severe. Depending on virus severity during the influenza season, annual deaths can range from a low of 3,000 to a high of about 49,000 people. Combined with pneumonia, influenza is the nation's eighth leading cause of death. Vaccination is safe and effective and the best way to help prevent influenza and its complications.

The Centers for Disease Control and Prevention recommends annual influenza vaccination for everyone 6 months of age and older to help protect against influenza and its complications. Adults younger than 65 years of age are among those with the lowest rates of immunization against influenza. Fluzone Intradermal vaccine, which is licensed for adults 18 through 64 years of age, is anticipated to provide an attractive immunization option for this age group.

Safety Information

The most common local and systemic adverse reactions to Fluzone Intradermal vaccine include erythema (redness), induration (firmness), swelling, pain, and pruritus (itching) at the vaccination site; headache, myalgia (muscle ache), and malaise. Other adverse reactions may occur. Fluzone Intradermal vaccine should not be administered to anyone with a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous dose of any influenza vaccine. The decision to give Fluzone Intradermal vaccine should be based on the potential benefits and risks, especially if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine. Vaccination with Fluzone Intradermal vaccine may not protect all individuals.

Before administering Fluzone® Intradermal vaccine or Fluzone® vaccine, please see full Prescribing Information available at www.sanofipasteur.us or www.vaccineshoppe.com

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

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 labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products 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 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, 2010. 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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