



Sanofi Pasteur Ships First 2015-2016 Seasonal Influenza Vaccine Doses in United States

- Leading influenza vaccine manufacturer to distribute more than 65 million doses to help protect people six months and older against the flu -

- Direct shipments to health care providers and distributors marks the start of the influenza immunization season -

SWIFTWATER, Pa. - July 14, 2015 - [Sanofi Pasteur](#), the vaccines division of [Sanofi](#), announced today that its first doses of Fluzone[®] (Influenza Vaccine) for the 2015-2016 influenza (“flu”) season have been released by the U.S. Food and Drug Administration (FDA) for shipment. This represents the first of more than 65 million total doses of seasonal influenza vaccine manufactured by Sanofi Pasteur that will be delivered to U.S. health care providers and pharmacies beginning in July and continuing throughout the 2015-2016 flu season.

According to the U.S. Centers for Disease Control and Prevention (CDC), the single best way to prevent influenza is to get an annual vaccination, which is recommended for everyone six months of age and older, with rare exception.^{i,ii} In fact, during the 2013-2014 season, the CDC estimated influenza vaccination prevented 7.2 million influenza-associated illnesses, 3.1 million medically attended illnesses, and 90,000 hospitalizations.ⁱⁱⁱ

“Influenza is a serious respiratory illness that is easily spread and can lead to severe complications involving the heart, lung, endocrine and other organ systems, potentially leading to death,” said David P. Greenberg, M.D., Vice President, Scientific & Medical Affairs, and Chief Medical Officer, Sanofi Pasteur U.S. *“Vaccination is important for high-risk age groups, including children and older adults. For older adults, vaccination is particularly important given their susceptibility to influenza and its complications due to an age-related weakening of the immune system.”*

Sanofi Pasteur will supply a wide portfolio of Fluzone influenza vaccine options this season to meet the immunization needs of multiple age groups, from children as young as 6 months of age through adults 65 years of age and older:

- **Fluzone High-Dose vaccine** is specially formulated for adults 65 years of age and older. As people age, the immune system weakens, which can put older adults at risk for influenza-related complications.^{iv} Clinical data demonstrated that Fluzone High-Dose vaccine was 24.2 percent more effective than Fluzone vaccine in preventing laboratory-confirmed influenza caused by any influenza viral type or subtype in association with influenza-like illness, in adults 65 years of age and older.^v
- **Fluzone Intradermal Quadrivalent vaccine**, licensed by the FDA in 2014 for adults 18 through 64 years of age, will be available for the first time this influenza season. Fluzone Intradermal Quadrivalent vaccine offers four-strain protection in a microinjection system that is convenient, efficient, and easy to use, allowing for streamlined administration by health care providers. The vaccine is administered directly into the skin through a 90% smaller, 1.5



mm microneedle. As the skin has a high concentration of immune cells, an intradermal vaccine is able to use the skin's natural defenses to induce a robust immune response. In addition, the microinjection system is ideal for vaccine administrators, since it has a pre-affixed needle and an integrated needle shield.

- **Fluzone Quadrivalent vaccine** helps protect against four influenza strains (two A strains and two B strains, in contrast to trivalent influenza vaccines, which help protect against three strains (two A strains and only one B strain). The influenza B strain is associated with high hospitalization and mortality rates, especially in children and young adults. In fact, on average, over multiple recent seasons, 34 percent of influenza-related deaths in children up to 18 years of age were due to influenza B.^{vi} Fluzone Quadrivalent vaccine is licensed for use in people six months of age and older.
- **Fluzone vaccine**, a trivalent influenza vaccine that protects against three influenza strains, is approved for use in people six months of age and older.

“Sanofi Pasteur is committed to helping people fight influenza by offering a broad range of vaccines for patients across multiple age groups,” added Dr. Greenberg. *“Patients should speak to their health care providers to determine which influenza vaccine option is most appropriate.”*

Health care providers who placed reservations with Sanofi Pasteur should expect to receive initial shipments by the end of August to support fall immunization campaigns.

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). Members of the public seeking a specific vaccine option, such as Fluzone High-Dose vaccine, Fluzone Intradermal Quadrivalent vaccine, or Fluzone Quadrivalent vaccine, can search for local providers at www.Fluzone.com.

About Fluzone Vaccines

Indication

Fluzone, Fluzone Quadrivalent, Fluzone Intradermal Quadrivalent, and Fluzone High-Dose vaccines are given to help prevent influenza disease caused by influenza A and B strains contained in each vaccine.

Fluzone and Fluzone Quadrivalent vaccines are given to people 6 months of age and older. Fluzone Intradermal Quadrivalent vaccine is given to people 18 through 64 years of age. Fluzone High-Dose vaccine is given to people 65 years of age and older.

Safety Information

Side effects to Fluzone, Fluzone Quadrivalent, Fluzone Intradermal Quadrivalent, and Fluzone High-Dose vaccines include pain, redness, and swelling at the injection site (also itching in adults receiving Fluzone Intradermal Quadrivalent vaccine); muscle aches, fatigue, headache, and fever (also irritability, abnormal crying, drowsiness, appetite loss, and vomiting in young children receiving Fluzone or Fluzone Quadrivalent vaccine). Itching, redness, swelling, and firmness at the injection site occurred more frequently with Fluzone Intradermal vaccine (containing 3 influenza strains) than with Fluzone vaccine. Other side effects may occur.

Fluzone, Fluzone Quadrivalent, Fluzone Intradermal Quadrivalent, and Fluzone High-Dose vaccines should not be administered to anyone with a severe allergic reaction (e.g., anaphylaxis) to



any vaccine component, including egg protein or thimerosal (the multidose vial is the only presentation containing thimerosal), or to a previous dose of any influenza vaccine.

Tell the doctor if you/your child has ever experienced Guillain-Barré syndrome (severe muscle weakness) after a previous dose of influenza vaccine. If you notice any other problems or symptoms following vaccination, please contact your health care professional immediately. Vaccination with Fluzone, Fluzone Quadrivalent, Fluzone Intradermal Quadrivalent, or Fluzone High-Dose vaccine may not protect all individuals.

For more information about Fluzone, Fluzone Quadrivalent, Fluzone Intradermal Quadrivalent, or Fluzone High-Dose vaccine, talk to your health care professional and see complete Patient Information.

About Influenza Vaccine Manufacturing

Direct shipments to health care providers and distributors mark the start of the influenza immunization season. While shipments will be ongoing through the influenza season, running from July through November 2015, Sanofi Pasteur began its seasonal manufacturing of the more than 65 million doses at the start of the year, following receipt of this year's influenza virus strains from the CDC.

As new influenza strains emerge and strain activity fluctuates throughout the year, each influenza season is unique. Global influenza surveillance monitors influenza activity to identify emerging and circulating strains, their respective levels of prevalence and their virulence.^{vii} Surveillance data are studied months before the upcoming influenza season to determine which circulating strains should be selected for the upcoming season's influenza vaccine.^{viii} Each February (for the Northern Hemisphere) and September (for the Southern Hemisphere), the World Health Organization (WHO) recommends strains for inclusion in influenza vaccines.

Influenza vaccine production is a complex process which takes months once the strain selection is made and received by manufacturers. Not only is vaccine production complex, it is also a highly regulated process that requires quality testing at each step in the process.

As the world's largest producer of seasonal influenza vaccine for both Northern and Southern Hemispheres, Sanofi Pasteur supplies more than 200 million doses worldwide annually.

About Influenza

Influenza is a serious respiratory illness that is easily spread and can lead to severe complications, even death. Each year in the United States, up to 20 percent of the population gets the flu and, on average, more than 200,000 people are hospitalized from influenza-related complications. Influenza 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.^{ix} Combined with pneumonia, influenza is the nation's eighth leading cause of death.^x Vaccination is safe and effective and the best way to help prevent influenza and its complications.

Children six months through eight years of age who have not previously received two doses of influenza vaccine may require two doses of vaccine for the 2015-2016 influenza season. Parents should consult their health care provider about the number of doses of influenza vaccine their child should receive. Individuals who are not immunized early in the season still have time to do so prior to the peak of influenza activity, which typically occurs in February.

Influenza vaccination is beneficial throughout the season, and even into the spring, as long as influenza viruses are still in circulation.



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 offers a broad 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, 2014. 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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