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FDA approves Influenza Vaccine for older people

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The U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application for Fluzone® High-Dose Quadrivalent (Influenza Vaccine) for use in adults 65 years of age and older.

Fluzone® High-Dose (Influenza Vaccine) was approved by the FDA in 2009 as a trivalent influenza vaccine, including two influenza A strains and one influenza B strain. Fluzone High-Dose Quadrivalent contains an additional influenza B strain. Fluzone High-Dose Quadrivalent is given to people 65 years of age and older to help prevent influenza disease caused by influenza A and B strains contained in the vaccine.

“Increasing protection and delivering improved influenza vaccines are critical to public health,” said David Loew, Sanofi Executive Vice President and head of Sanofi Pasteur. “We are excited to build upon the success of trivalent Fluzone High-Dose with this FDA approval to expand protection for an additional B strain. We have submitted filings with additional regulatory bodies outside the U.S. and anticipate approval in the European Union next spring.”

This approval is the final step toward the company’s complete transition to quadrivalent influenza vaccines in the U.S. Fluzone High-Dose Quadrivalent will be made available for immunization efforts during the 2020-2021 influenza season. Sanofi Pasteur will continue to deliver and offer the trivalent formulation of Fluzone High-Dose through the end of the 2019-2020 influenza season.

FDA approval was based on data from a Phase 3 immunogenicity and safety study, in which Fluzone High-Dose Quadrivalent achieved the primary endpoint of non-inferior immunogenicity compared to two trivalent formulations of Fluzone High-Dose, each containing one of the two influenza B strains recommended for inclusion in the vaccine for the 2017-2018 influenza season. In a secondary endpoint of the trial, each B strain in Fluzone High-Dose Quadrivalent induced a superior immune response compared to the trivalent formulation not containing the corresponding B strain.

Rates of local and systemic reactions that occurred following immunization with Fluzone High-Dose Quadrivalent were similar to those induced by trivalent formulations of Fluzone High-Dose. The most common reactions occurring after administration were injection-site pain (41.3 percent), myalgia (22.7 percent), headache (14.4 percent), and malaise (13.2 percent). Onset usually occurred within the first three days after vaccination, and the majority of solicited reactions were resolved within three days of vaccination. Results from the study were published in Vaccine in September 2019.

Fluzone High-Dose is the first and only influenza vaccine proven to provide superior efficacy compared to Fluzone® (Influenza Vaccine) in adults 65 years of age and older, based on results in a randomized controlled trial.This study evaluated nearly 32,000 adults 65 years of age and older over two influenza seasons in the U.S. and Canada. Results showed that Fluzone High-Dose prevented 24 percent more cases of influenza caused by any circulating influenza strain and 51 percent more cases of influenza caused by strains similar to those contained in the vaccine compared to Fluzone. Based on data from Fluzone High-Dose, solicited injection site reactions and systemic adverse reactions were slightly more frequent after vaccination with Fluzone High-Dose compared to a standard-dose vaccine.

As of the end of the 2018-2019 influenza season, over 112 million doses of Fluzone High-Dose have been distributed in the U.S. In the 2018-2019 influenza season, nearly two-thirds of U.S. adults 65 years of age and older who received an influenza vaccine received Fluzone High-Dose.