Fluzone® High-Dose Quadrivalent (influenza vaccine) – New formulation approval

- On November 4, 2019, Sanofi announced the FDA approval of Fluzone High-Dose Quadrivalent (influenza vaccine), for active immunization for the prevention of influenza caused by influenza A subtype viruses and type B viruses contained in the vaccine. Fluzone High-Dose Quadrivalent is indicated for use in persons 65 years of age and older.
    - Previously, Fluzone High-Dose was available as a trivalent vaccine, including two influenza A strains and one influenza B strain.
    - Fluzone High-Dose Quadrivalent contains an additional influenza B strain.
- The FDA approval of Fluzone High-Dose Quadrivalent was based on data from an immunogenicity and safety study enrolling 2,670 adults aged 65 years and older. Patients received one dose of Fluzone High-Dose Quadrivalent or one of two formulations of Fluzone High-Dose. The objective of the study was to demonstrate immunologic non-inferiority of Fluzone High-Dose Quadrivalent to Fluzone High-Dose.
    - Fluzone High-Dose Quadrivalent achieved the primary endpoint of non-inferior immunogenicity vs. the two trivalent formulations of Fluzone High-Dose.
    - In addition, in a secondary endpoint of the trial, each B strain in Fluzone High-Dose Quadrivalent induced a superior immune response vs. the trivalent formulation not containing the corresponding B strain.
- Fluzone High-Dose Quadrivalent is contraindicated in persons who have had a severe allergic reaction to any component of the vaccine, including egg protein, or after a previous dose of any influenza vaccine.
- Warnings and precautions of Fluzone High-Dose Quadrivalent include Guillain-Barré syndrome, preventing and managing allergic reactions, altered immunocompetence, limitations of vaccine effectiveness, febrile or acute disease, and syncope.
- The most common injection-site reaction with Fluzone High-Dose Quadrivalent use was pain (41.3%). The most common solicited systemic adverse event was myalgia (22.7%).
- The recommended dose of Fluzone High-Dose Quadrivalent should be administered as a single 0.7 mL injection by the intramuscular (IM) route in adults 65 years of age and older.
    - The preferred site for IM injection is the deltoid muscle. The vaccine should not be injected into the gluteal area or areas where there may be a major nerve trunk.
- Sanofi plans to launch Fluzone High-Dose Quadrivalent in the fall of 2020, in time for the 2020 -2021 flu season. Fluzone High-Dose Quadrivalent will be available as prefilled syringes containing 0.7 mL suspension.

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