MenQuadfi™ (meningococcal [Groups A, C, Y, W] conjugate vaccine) – New drug approval

- On April 24, 2020, Sanofi announced the FDA approval of MenQuadfi (meningococcal [Groups A, C, Y, W] conjugate vaccine), for active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y.
    - MenQuadfi is indicated for use in individuals 2 years of age and older.
    - MenQuadfi does not prevent *N. meningitidis* serogroup B disease
- MenQuadfi is the only FDA-approved quadrivalent meningococcal vaccine indicated for persons 2 through 56 years of age and older.
- The effectiveness of MenQuadfi for primary vaccination was assessed in four studies, and for booster vaccination in one additional study in a total of nearly 5,000 patients 2 years of age and older. To infer effectiveness of MenQuadfi, immunogenicity was assessed using a serogroup-specific serum bactericidal assay with exogenous human complement (hSBA). The hSBA geometric mean titers (GMTs) and proportion of participants who achieved hSBA seroresponse were evaluated.
    - Non-inferiority of MenQuadfi seroresponse rates vs. those for comparator vaccines was demonstrated for all 4 serogroups in individuals 2 years of age and older who received a primary vaccination and in individuals 15 years of age and older who received a booster vaccination at least 4 years following a previous dose of a meningococcal (Groups A, C, W, Y) conjugate vaccine.
- MenQuadfi is contraindicated in patients with severe allergic reaction to any component of the vaccine, or after a previous dose of MenQuadfi or any other tetanus toxoid-containing vaccine.
- Warnings and precautions for MenQuadfi include management of acute allergic reactions; altered immunocompetence; syncope; Guillain-Barré syndrome; tetanus immunization; and limitations of vaccine effectiveness.
- The most common adverse reactions (≥ 10%) with MenQuadfi following a primary dose were injection site pain (injection site erythema and swelling were also reported for children 2 through 9 years of age), malaise, myalgia, and headache.
    - In adolescents and adults, rates of solicited adverse reactions following a booster dose were comparable to those observed following primary vaccination.
- MenQuadfi is administered as a single 0.5 mL injection intramuscularly. For the primary vaccination, individuals 2 years of age and older receive a single dose. For booster vaccination, a single dose of MenQuadfi may be administered to individuals 15 years of age and older who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of meningococcal (Groups A, C, W, Y) conjugate vaccine.

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- Sanofi plans to launch MenQuadfi in 2021. MenQuadfi will be available as a 0.5 mL solution in a single-dose vial.