Vaxneuvance™ (pneumococcal 15-valent conjugate) – New vaccine approval

- On July 16, 2021, Merck announced the FDA approval of Vaxneuvance (pneumococcal 15-valent conjugate) vaccine for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.

- The approval of Vaxneuvance was based on data from seven randomized, double-blind clinical studies assessing safety, tolerability, and immunogenicity in adults.

- Clinical data showed that immune responses elicited by Vaxneuvance were non-inferior to the currently available 13-valent pneumococcal conjugate vaccine (PCV13) for the 13 shared serotypes, as assessed by opsonophagocytic activity geometric mean titers.
- Additionally, immune responses for Vaxneuvance were superior to PCV13 for shared serotype 3 and for the two serotypes unique to Vaxneuvance, 22F and 33F.

- Vaxneuvance is contraindicated in patients with a severe allergic reaction (eg, anaphylaxis) to any component of Vaxneuvance or to diphtheria toxoid.

- A warning and precaution for Vaxneuvance is altered immunocompetence.

- The most common adverse reactions with Vaxneuvance use in individuals 50 years of age or older were injection-site pain (66.8%), myalgia (26.9%), fatigue (21.5%), headache (18.9%), injection-site swelling (15.4%), injection-site erythema (10.9%) and arthralgia (7.7%).

- The most common adverse reactions with Vaxneuvance use in individuals 18 through 49 years of age were injection-site pain (75.8%), fatigue (34.3%), myalgia (28.8%), headache (26.5%), injection-site swelling (21.7%), injection-site erythema (15.1%) and arthralgia (12.7%).

- The recommended administration of Vaxneuvance is a single 0.5 mL dose given intramuscularly.

- The U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices is expected to meet in October to discuss and make recommendations on the use of Vaxneuvance in adults.

- Merck's launch plans for Vaxneuvance are pending. Vaxneuvance will be available as a suspension for intramuscular injection supplied in a 0.5 mL single-dose prefilled syringe.