Capvaxive™ (pneumococcal 21-valent conjugate vaccine) – New vaccine approval

- On June 17, 2024, Merck announced the FDA approval of Capvaxive (pneumococcal 21-valent conjugate vaccine), for:
    - Active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* (*S. pneumoniae*) serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.
    - Active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.

- The indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

- Capvaxive includes eight serotypes not covered by other currently approved pneumococcal vaccines.
    - Based on CDC data, these serotypes were responsible for approximately 27% of invasive pneumococcal disease (IPD) cases in adults 50 years of age and older and approximately 30% in adults 65 years of age and older.

- The efficacy of Capvaxive was established based on immunogenicity studies in both vaccine-naïve and vaccine-experienced patients. Refer to the Capvaxive drug label for complete study results.

- Warnings and precautions for Capvaxive include management of allergic reactions and altered immunocompetence.

- The most common solicited adverse reactions (> 10%) with Capvaxive use in individuals 18 through 49 years of age were: injection-site pain, fatigue, headache, myalgia, injection-site erythema, and injection-site swelling. In individuals 50 years of age and older, they were injection-site pain, fatigue, and headache.

- Capvaxive is administered as a single 0.5 mL intramuscular injection.

- The CDC's Advisory Committee on Immunization Practices (ACIP) is expected to meet on June 27 to discuss and make recommendations for the use of Capvaxive in adults.

- Depending on the recommendations by the CDC, Merck plans to launch Capvaxive as soon as late July 2024. Capvaxive will be available as a 0.5 mL single-dose syringe.