## Prevnar 20™ (pneumococcal 20-valent conjugate vaccine) – New drug approval

- On June 8, 2021, Pfizer announced the FDA approval of Prevnar 20 (pneumococcal 20-valent conjugate vaccine), for active immunization for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older.
    - This indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- Following this FDA approval, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) is expected to meet in October to discuss and update recommendations on the safe and appropriate use of pneumococcal vaccines in adults.
- Prevnar 20 is a conjugate vaccine that helps protect against 20 serotypes responsible for the majority of invasive pneumococcal disease and pneumonia.
- The approval of Prevnar 20 was based on Phase 1 and 2 studies, and three Phase 3 studies describing the safety and evaluating the immunogenicity of the vaccine. More than 6,000 adult subjects 18 years and older participated in the three Phase 3 trials, including adults 65 years of age and older, vaccine-naïve adults, and adults with prior pneumococcal vaccination.
    - Refer to the Prevnar 20 drug label for complete trial results.
- Warnings and precautions for Prevnar 20 include management of acute allergic reactions and altered immunocompetence.
- In adults 18 through 59 years of age, the most commonly reported solicited adverse reactions (> 10%) with Prevnar 20 use were pain at the injection site, muscle pain, fatigue, headache, and arthralgia and injection site swelling.
- In adults 60 years of age and older, the most commonly reported solicited adverse reactions (> 10%) with Prevnar 20 use were pain at the injection site, muscle pain and fatigue, headache, and arthralgia.
- Prevnar 20 is administered intramuscularly as a single dose.

- Pfizer's launch plans for Prevnar 20 are pending. Prevnar 20 will be available as a 0.5 mL suspension for intramuscular injection, supplied in a single-dose pre-filled syringe.