FDA Approves Capvaxive Pneumonia Vaccine

The FDA approved the pneumococcal 21-valent conjugate vaccine (PCV21; Capvaxive, Merck) for adults to prevent against invasive pneumococcal disease and pneumonia caused by *Streptococcus pneumoniae*. The vaccine has the potential to reduce the 150,000 hospitalizations and 41,000 deaths that occur as a result of pneumococcal pneumonia each year in the United States, according to the CDC.

The FDA based its decision on results from three phase 3 clinical studies that demonstrated the safety and optimal immunogenicity of the PCV21 vaccine. The STRIDE-3 trial (ClinicalTrials.gov Identifier: NCT05425732), which compared the efficacy of PCV21 with pneumococcal 20-valent conjugate vaccine (PCV20) in adults who had not received a pneumococcal vaccine, revealed PCV21 had a comparable safety profile to PCV20 and was noninferior to PCV20.

Additionally, in adults older than 50 years of age, STRIDE-3 showed PCV21 was superior to PCV20 for 10 of 11 serotype polysaccharides included in PCV21 but not PCV20, and noninferior to PCV20 for the 10 serotypes shared with both vaccines.

The serotypes shared with both vaccines are 3, 6A, 7F, 8, 10A, 11A, 12F, 19A, 22F and 33F; the serotypes contained only in PCV21 include 9N, 15A, 16F, 17F, 20A, 23A, 23B, 24F, 31 and 35B.

The second study the FDA reviewed in approving PCV21 was STRIDE-5 (NCT05526716), in which adults 50 and older were administered PCV21 concomitantly or sequentially with quadrivalent influenza vaccine (QIV). At one month after vaccination, PCV21 administered concomitantly with QIV was noninferior to PCV21 given sequentially with QIV for 20 of 21 serotypes in PCV21, as well as for three of four influenza strains in QIV, for the primary immunogenicity end points.

STRIDE-6 (NCT05420961) assessed serotype-specific opsonophagocytic activity (OPA) geometric mean titers in patients older than 50 who received a pneumococcal vaccine at least one year before enrollment. These vaccine-experienced participants were separated into three cohorts according to vaccination history:

- cohort 1, PPSV23 (pneumococcal 23-valent polysaccharide vaccine);
- cohort 2, PCV13 (pneumococcal 13-valent conjugate vaccine); and
- cohort 3, PPSV23 followed or preceded by PCV13, PPSV23 preceded by PCV15 (pneumococcal 15-valent conjugate vaccine) or PCV15 alone.

- In cohort 11, OPA responses from PCV21 were comparable to PCV15 for the six common serotypes, and higher for the 15 unique serotypes and serotype 15B. In cohort 2, OPA responses elicited by PCV21 were comparable to PPSV23 for the 12 common serotypes and serotype 15B, and higher for the nine unique serotypes. Overall, OPA responses to PCV21 were similar across the three cohorts.
- The FDA-approved PCV21 includes eight serotypes, which are not covered by other approved pneumococcal vaccines, responsible for 30% of invasive pneumococcal disease cases in adults older than 65: 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B. Its active ingredients are bacterial sugars from 21 types of pneumococcus, each linked to a protein, which covers the S. pneumoniae serotypes responsible for about 84% of invasive pneumococcal disease in adults older than 50. The vaccine's inactive ingredients include L-histidine, sodium chloride, water and polysorbate 20. Headaches, injection site pain and fatigue were the most commonly reported adverse reactions after vaccination.

- “Today’s approval is a testament to our population-specific strategy behind Capvaxive, which demonstrated robust immunogenicity in a range of adult populations and is driven by a deep understanding of pneumococcal disease,” said Dean Y. Li, MD, PhD, the president of Merck Research Laboratories, in a company news release. “We are proud to provide Capvaxive as a new option specifically designed to help protect against the majority of invasive pneumococcal disease-causing serotypes in adults.”

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