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Merck's Newly Approved Capvaxive Could Have Edge Over Prevnar 20 In Adults

by Jessica Merrill

The 21-valent pneumococcal vaccine will face an entrenched competitor in Pfizer's Prevnar 20, but Merck believes Capvaxive has a competitive advantage because it protects against serotypes specific to adults.

Merck & Co., Inc.'s 21-valent pneumococcal vaccine Capvaxive, approved by the US Food and Drug Administration on 17 June for adults 18 and older, presents a new rival to Pfizer's 20-valent vaccine Prevnar 20, and could better target the adult population.

Pfizer's Prevnar dominates the market and has a long heritage for adults and children, but Merck & Co. believes Capvaxive has an advantage in the adult market because the vaccine is designed specifically to treat serotypes that are the most prevalent in adults, some of which are not included in Prevnar 20.

Capvaxive, previously called V116, includes eight unique serotypes that are not covered by Prevnar 20 that are responsible for approximately 27% of invasive pneumococcal disease in adults 50 years and older and approximately 30% in adults 65 years of age and older.

Altogether, based on data from the US Centers for Disease Control and

Key Takeaways

- Merck believes Capvaxive has an advantage in the adult market because the vaccine is designed to treat serotypes that are the most prevalent in adults, some of which are not included in Prevnar 20.
- The CDC's ACIP will review recommendations during an upcoming June meeting and could recommend routine vaccination in a younger population of adults aged 50-plus.
- The wholesale acquisition cost (WAC) of Capvaxive is $287, while the WAC price of

Prevention from 2018-2021, Capvaxive covers the serotypes responsible for approximately 84% of invasive pneumococcal disease in adults 50 and older and 85% of cases in adults 65 and older, versus 52% and 51%, respectively, for Prevnar 20, Merck said.

Prevnar 20 is $260.81.

A Possible 50+ Market For Adults

Given its efficacy specific to adults, Merck is hoping that Capvaxive may be able to get a recommendation from CDC's Advisory Committee on Immunization Practices (ACIP) for routine vaccination in adults 50 and older; current recommendations for pneumococcal vaccines are for routine vaccinations for adults 65 and older or in adults 19-64 who are immune-compromised or have underlying medical conditions. ACIP is scheduled to meet 26-28 June and will discuss recommendations for Capvaxive. (Also see "*Change Is Constant For Pneumococcal Vaccines: US CDC Prepares For Merck's V116*" - Pink Sheet, 17 Apr, 2024.)

Merck CEO Rob Davis discussed the possible broader market opportunity during the company's first quarter sales and earnings call on 25 April and said the vaccine's higher efficacy in adults makes a stronger value case.

"We continue to believe that the value proposition of V116 is very compelling," he said. "It's going to be a very cost-effective vaccine and, as a result, I think that's why you started to see the ACIP ask questions about the 50 to 65 age cohort as well as the 65-plus," he said.

Capvaxive Versus Prevnar 20 In Adults

Serotypes covered by Capvaxive: 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B

Serotypes covered by Prevnar 20: 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14,15B, 18C, 19A, 19F, 22F, 23F and 33F

The wholesale acquisition cost (WAC) of Capvaxive is $287, while the WAC price of Prevnar 20 is $260.81. The list prices of the vaccines do not reflect any rebates or discounts.

Pfizer Prepared To Defend

Prevnar is well positioned to continue to dominate the pneumococcal vaccine market, however, because Prevnar 20 is approved for children six weeks of age and older while Capvaxive is not, and the pediatric market represents a substantially larger market than the adult one. Merck is developing another vaccine, V117, that is in early clinical development and is designed specifically to target the serotypes that cause disease in children.

Merck does commercialize a 15-valent pneumococcal vaccine Vaxneuvance that is approved for individuals 6 weeks of age and older. Vaxneuvance was approved by the FDA in 2021 for adults initially, back-to-back with the approval of Pfizer's Prevnar 20. (Also see "*Pneumococcal Vaccines Market Snapshot: Pfizer And Merck Face Off*" - Scrip, 15 Nov, 2021.)

Sales of Vaxneuvance have picked up more recently, but the vaccine remains well behind Prevnar 20, partly because it is recommended in sequential dosing with Merck's older vaccine Pneumovax 23, while Prevnar 20 is recommended as a single dose. Vaxneuvance generated $219m in the first quarter of 2024, compared to $1.69bn for Pfizer's Prevnar franchise.

Pfizer was asked about the anticipated competition from Merck during its first quarter call on 1 May and downplayed the impact in the adult market, where the commercial market is shrinking.

"There are increasingly fewer eligible 65-plus adults, and then the 19 to 64 underlying medical conditions population is obviously more difficult to activate" Pfizer chief commercial officer Aamir Malick said during the call.

Prevnar 20 holds a 98% share of the adult market, he added, noting the company will defend its commercial leadership, including through competitive rebating.

"It's also important to note that in the non-retail setting, many organized customers have a preference for workflow management to stock one vaccine that satisfies all the current ACIP recommendations," he added.

The Capvaxive approval was based on the results of Merck's pivotal Phase III STRIDE-3 trial, evaluating the vaccine compared to Prevnar 20 in adults 18 years of age and older who had not previously received a pneumococcal vaccine. Data from the Phase III STRIDE-5 and STRIDE-6 trials in vaccine-naïve and vaccine-experienced adults also supported the filing.