Evaluate Vantage

June 23, 2020

Merck and Pfizer square up for pneumococcal vaccine fight

Amy Brown

The rivals have taken different strategies with next-gen pneumococcal vaccines, which will be fighting for a blockbuster market that is Pfizer's to lose.

Pneumococcal vaccines are hugely successful products – global sales reached $7.5bn last year – and the market for now is controlled by Pfizer with Prevnar 13. But the company might be facing its first real challenge in the coming years, from a new project being developed by Merck & Co.

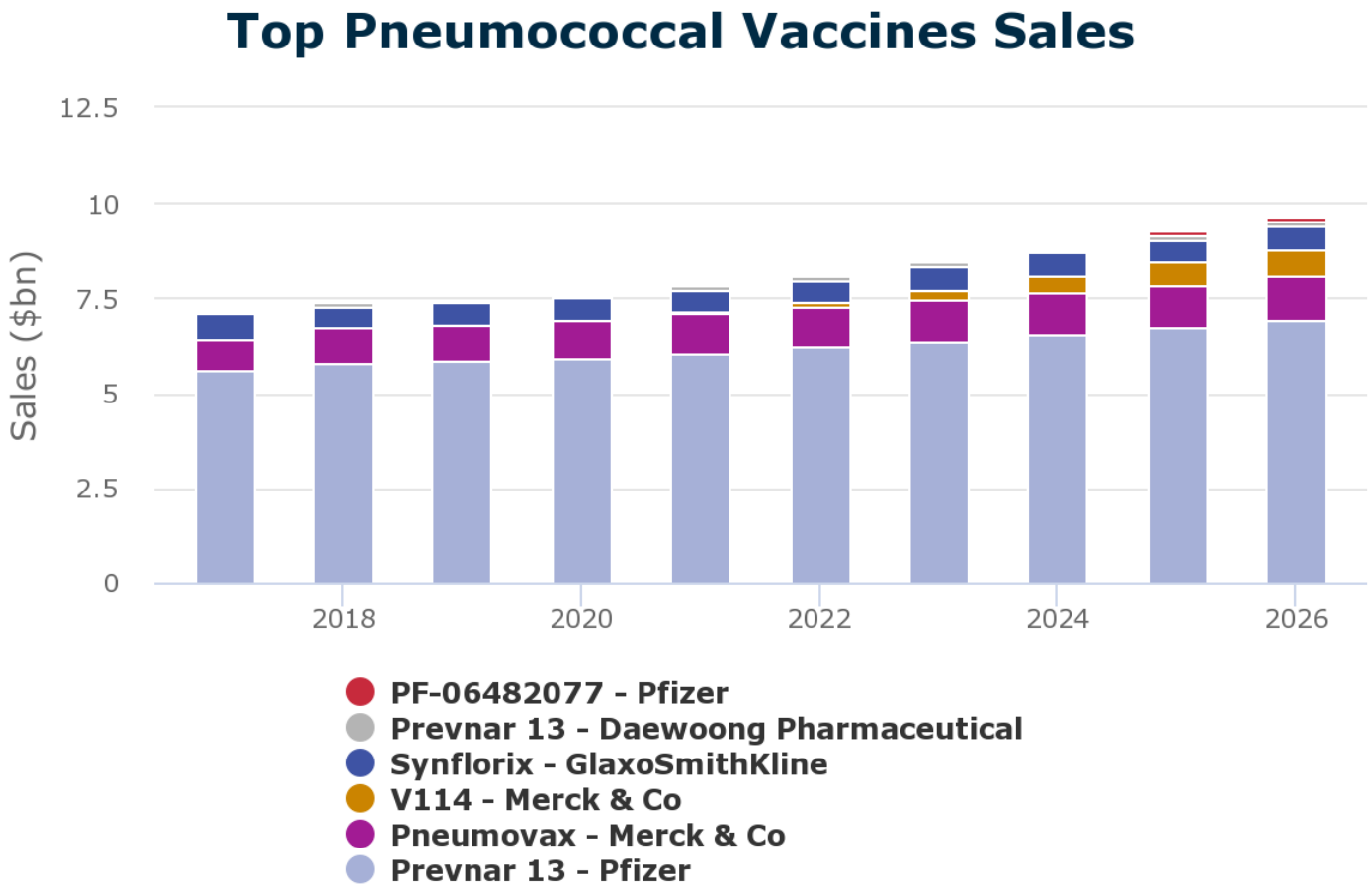
V114 adds two more serotypes on top of Prevnar's 13, strains of the *Streptococcus pneumoniae* bacterium that Merck says are associated with more serious, invasive infections. Pfizer is not sitting still, however, and has 20vPnC, a 20-valent project, in late-stage development.

The broader the better in one shot is the thinking here: Pfizer has claimed that the five additional serotypes in 20vPnC (PF-06482077) can provide coverage against around 33% more strains in adults and 42% more strains in infants than V114.

Merck, meanwhile, is going for a more targeted approach, noting that, while broader is important, maintaining efficacy is also vital. As vaccination programmes moved from the older Prevnar 7 to the 13-valent product, breakthrough infections have been seen in certain serotypes. Perhaps the company thinks it can more effectively maintain durability with a tighter focus.

As well as V114, Merck has two other projects. V116 is being developed to target residual pneumococcal disease in adults, while V117 is described as a "next-generation" paediatric vaccine. The latter is not yet in the clinic, and V116 has only just arrived, so V114 is the project to watch for now.

It is also worth remembering that Merck already sells Pneumovax, a 23-valent vaccine; uniquely, this is a polysaccharide vaccine, and is therefore less immunogenic than conjugate vaccines like Prevnar 13 and V114. Polysaccharide vaccines give shorter protection and are less useful in infants or older people, who have weaker immune systems, so Pneumovax's commercial potential has been limited.



Little phase III data have been released on either V114 or 20vPnC, so it is hard to say yet which strategy might be more successful. Both need to prove non-inferiority to Prevnar 13, as well as responses to new strains – and that they confer lasting protection.

In March Pfizer said 20vPnC had shown itself non-inferior to Prevnar 13, and to Pneumovax on six of seven serotypes that are included in that product, in adults. One of the new seven serotypes missed non-inferiority criteria by a small margin. Results from two further pivotal trials are due in the coming months.

Merck meanwhile has a huge phase III programme under way, with 16 studies on the go. The company revealed this week that V114 elicited immune responses to all serotypes in HIV-positive patients, although nothing was said about non-inferiority. Further readouts are also expected this year.

Phase II data in healthy infants last year showed the jab to be non-inferior to Prevnar 13 on all serotypes included in that vaccine, and that it produced immune responses to the two additional strains.

Merck does have one clear advantage here: it is ahead in the infant population. The childhood vaccine market makes up around 80% of pneumococcal vaccine sales. Pfizer has only just begun pivotal development of 20vPnC in children, announcing the start of two trials this week.

Both companies plan to seek for approvals for their respective projects by the end of this year, in adults. However, analysts believe that Merck is around 1.5 years ahead in the crucial infant setting. Assuming that the project convinces clinically, Merck will be highly motivated to make the most of what could be a substantial time advantage.