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Abrysvo Data In Younger Adults Could Give Pfizer An Edge Over GSK

by Jessica Merrill

Pfizer plans to use the positive Phase III data in adults 18-59 to expand use of the RSV vaccine.

The results of the Phase III MONeT trial testing *Pfizer Inc.*'s respiratory syncytial virus (RSV) vaccine in adults 18-59 at risk of developing severe disease present an opportunity for the firm to target Abrysvo to younger patients than its top rival, *GSK plc*.

Abrysvo and GSK's Arexvy are both currently approved for adults 60 and older, but GSK is already ahead in an effort to expand the use to younger patients. GSK announced positive Phase III data results in adults 50-59 at increased risk for RSV due to certain medical conditions last fall and submitted the data to the US Food and Drug Administration. (Also see "*In Competitive RSV Market, GSK Aims To Be First For Adults 50-59*" - Scrip, 25 Oct, 2023.)

GSK's application has a 7 June action date and if it is approved, the US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) is expected to discuss the recommendation at a meeting slated for 26-28 June. (Also see "*US CDC's Adult RSV Vaccine Recommendations In Flux With Impending FDA Approvals*" - Pink Sheet, 29 Mar, 2024.)

Key Takeaways

- Positive results from the Phase III MONeT trial testing the RSV vaccine Abrysvo in adults 18-59 at risk of developing severe disease could give Pfizer a new niche over rival GSK.
- GSK is already ahead in an effort to expand the use of Arexvy to younger individuals with an application pending at FDA for adults 50-59.
- Some conditions can put individuals at higher risk of RSV, including asthma, diabetes and COPD.

With the positive data on Abrysvo announced 9 April, which Pfizer plans to submit to regulatory authorities, the company could carve out its own niche in even younger patients, though the market opportunity is smaller. Among US adults, 24.3% of those 50 to 64 years of age have a chronic condition that puts them at risk of severe RSV disease, while among those 18 to 49, the number drops to about 9.5%, according to Pfizer. Some conditions that can put individuals at higher risk of RSV include asthma, diabetes and chronic obstructive pulmonary disease.

The two vaccines launched at the same time last fall but GSK's Arexvy emerged as the dominant product following the first vaccination season. (Also see "*GSK Can Finally Claim A Turnaround Thanks To Arexvy's Blockbuster Launch*" - Scrip, 31 Jan, 2024.) While both vaccine launches were powerful growth drivers, Arexvy generated £1.24bn ($1.57bn) in 2023 while Abrysvo generated $890m.

Pfizer CEO Albert Bourla acknowledged that the company flubbed the launch by allowing GSK to beat it to the retail market but has vowed to investors not to repeat the mistake. (Also see "*J.P. Morgan Day One: Novartis Reveals Two Deals, Pfizer's Bad Year, Bristol's Wobbly Growth*" - Scrip, 9 Jan, 2024.) Abrysvo already has one other differentiating lever versus Arexvy, which is that it is also approved as a maternal vaccine to be administered to pregnant women to protect infants at birth. (Also see "*Pfizer's Abrysvo Is First Maternal Vaccine For RSV To Protect Infants*" - Scrip, 21 Aug, 2023.)

The MONeT study reached both of its co-primary immunogenicity endpoints and the primary safety endpoint. Participants in two subgroups, RSV-A (those with certain chronic medical conditions) and RSV-B (those who are immunocompromised), demonstrated neutralizing responses non-inferior to the responses in the Phase III RENOIR study that was the basis of Abrysvo's approval in adults 60 and older. A four-fold increase in serum-neutralizing titers was also observed for RSV-A and RSV-B one month following administration of Abrysvo compared to pre-vaccination. Safety findings were consistent with previous findings.

Substudy A is a double-blind study that enrolled 681 adults aged 18-59 with chronic conditions while Substudy B is an open-label study that enrolled approximately 200 immunocompromised adults 18 and older, roughly half of whom were 60 and older.

Another potential growth opportunity for both Abrysvo and Arexvy would be if the CDC were to change its recommendations for RSV vaccines from one based on "shared clinical decision-making" with an individual's physician to a "universal recommendation" at a specific age cutoff, something ACIP is reviewing.

When the vaccines were approved last year and recommended for use by the CDC it was with the shared clinical decision-making status, a recommendation used when individuals may benefit but broad vaccination of a group is viewed as unlikely to make population-level impacts. (Also

see "*Pfizer, GSK US RSV Vaccine Uptake Likely Hurt By ACIP's Weaker Recommendation*" - Pink Sheet, 21 Jun, 2023.)