KPMG

RSV Prevention Landscape: Q423 Update

December 2023

—

kpmg.com/uk

Key points:

01 **RSV seasonality is returning to trend, however, the overall burden of respiratory viruses on healthcare systems remains high**

02 **The first RSV vaccines were launched in Q323 and demonstrated better-than-expected sales in their first quarter**

03 **A slimmer near-term pipeline bodes well for the commercial outlook for launched products**

04 **There are opportunities to further optimise vaccine uptake through the collection of real-world data and awareness-raising**

05 **The development of combination vaccines could drive a further shift in the prevention of respiratory viruses**

06 **Prevention of respiratory viruses will remain a focus for manufacturers and for healthcare systems**

In March 2023, we published an overview of the respiratory syncytial virus (RSV) prevention landscape, including expected opportunities and challenges (1). Now that initial financial results have been reported for the first products launched, we provide an update in terms of developments that have occurred over 2023 and an updated view for the landscape in 2024 and beyond.

2023 has seen the approval and launch of two RSV vaccines from GSK and Pfizer and the regulatory submission of a further one from Moderna - for which approval is expected in 2024 (2)(3)(4). A high unmet medical need associated with RSV, the return of normal RSV seasonality, and a continued burden on healthcare systems from respiratory viruses have combined to drive demand for the new vaccines (5)(6)(7). The initial financial performance of these products (Q323) has exceeded expectations, which, along with a slimmer near-term RSV prevention pipeline, bodes well for the manufacturers (8). These companies now have the opportunity to further optimize uptake through robust epidemiological surveillance and steps to increase awareness of RSV.

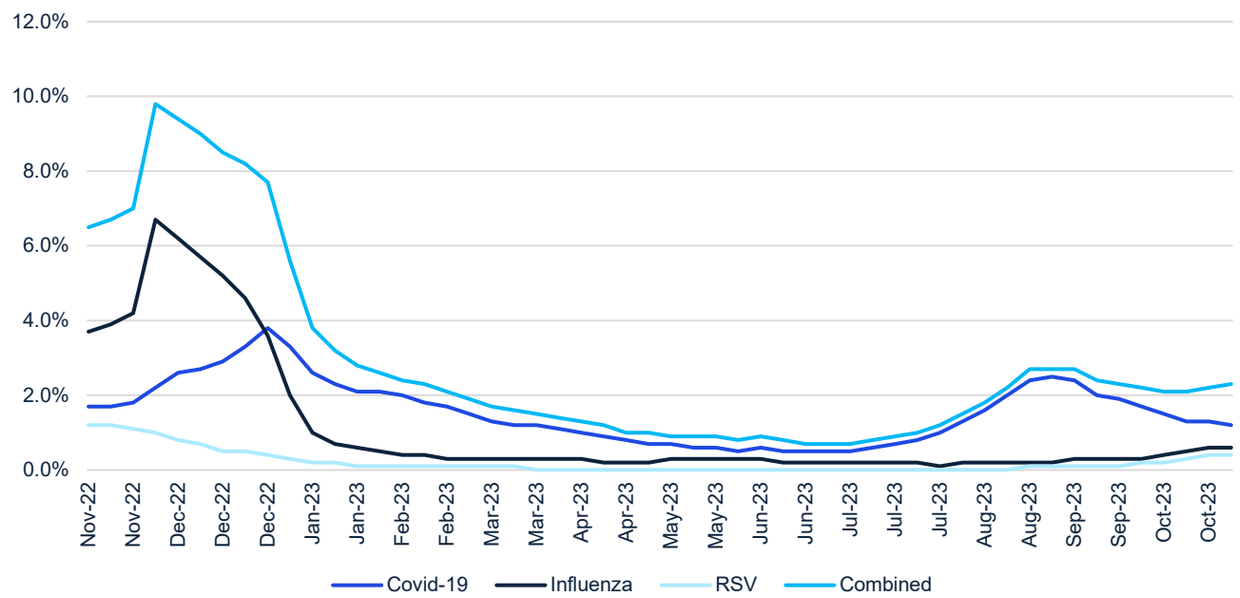
RSV seasonality is expected to return to long-term trend, however, the overall burden from respiratory viruses on healthcare systems is likely to remain high. The seasonality of RSV was disrupted during the Covid-19 pandemic with circulation historically low during the 2020–21 season and beginning earlier and continuing longer during the 2021–22 season compared with pre-pandemic annual seasonality (9). Going forward, a trend that more closely resembles historical norms is expected; according to the US CDC 'experts anticipate that RSV is likely to return to normal season patterns [in 2023] following a severe season last year' (6). However, the overall burden of respiratory disease on healthcare systems remains high due to the combined impact of Covid-19, RSV, and influenza.

Combined, these three viruses accounted for 10% of emergency department visits at the peak of the virus season in 2022 equating to significant resource and expense. This reiterates the importance of optimising vaccine uptake across these 3, now largely preventable, illnesses (7).

Ongoing burden from RSV, Covid-19, and influenza reiterates importance of vaccine uptake

US: Weekly Emergency Department Visits by Viral Respiratory Illness Type, as a Percent of All Emergency Department Visits

Source: US CDC

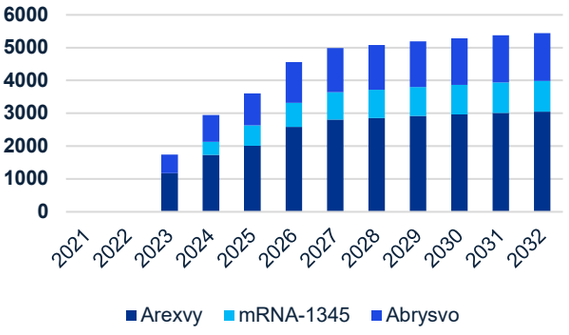


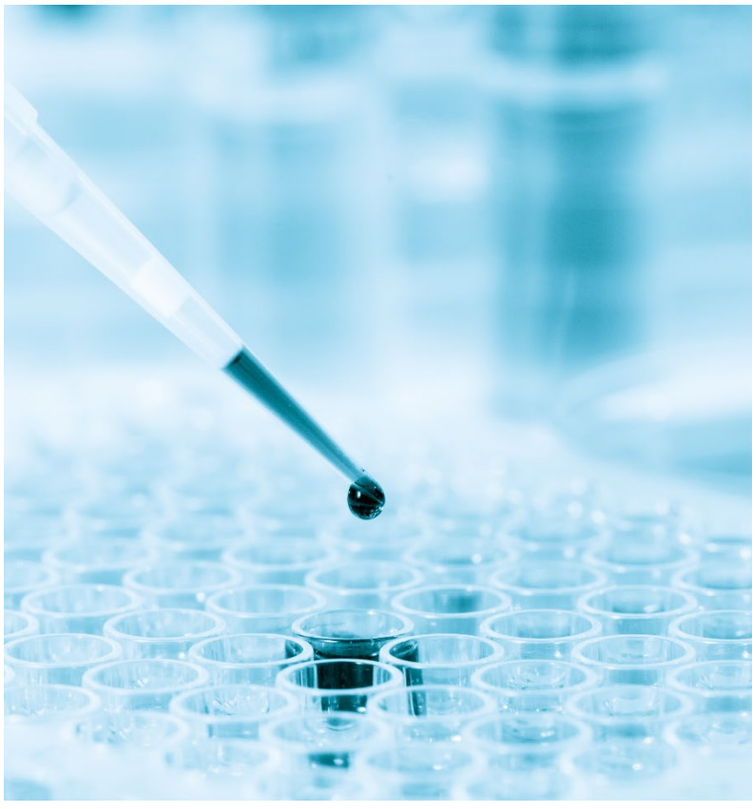
The first launched RSV vaccines demonstrated better than-expected sales in Q323. In early November 2023, GSK and Pfizer announced Q323 results detailing the first sales of their RSV vaccines, Arexvy and Abrysvo respectively (10)(11). Arexvy in particularly beat analyst consensus estimates by a significant margin reaching GBP709 (USD850mn) in sales for the quarter, with retail channels accounting for over 90% of those sales. Abrysvo's slightly later launch generated GBP304mn (USD375mn). Moderna looks set to join the market in 2024 having filed for regulatory approval for its mRNA RSV vaccine mRNA-1345 in July 2023.

RSV vaccines sales will be driven by large addressable market

RSV vaccines sales forecast (USDmn)

Source: Biomedtracker (with KPMG adjustments based on Q323 product sales)





A slimmer near-term pipeline bodes well for the manufacturers of launched products. Looking forward, the prospects for these frontrunners are improved by halts to the programmes of potential competitors. RSV vaccine development programmes (for the elderly segment) at Johnson & Johnson and Bavarian Nordic have been discontinued in March and July 2023 respectively leaving a dearth of competition to GSK, Pfizer, & Moderna (12)(13). In the paediatric & maternal segment, the next most advanced vaccine candidates, being developed by Sanofi, Meissa, and Codagenix, are unlikely to reach the market until 2025 at the earliest, giving Pfizer time to grow revenues in this market. However, Pfizer faces significant pressure in this space from Beyfortus an RSV therapeutic co-commercialized by AstraZeneca and Sanofi (14).

Marketed RSV products and pipeline

Source: company press releases

Elderly Segment

Company	Segment	Product	Approval	Launch
GSK	Elderly	Arexvy	FDA: May 2023, EU: June 2023	Q323
Pfizer	Elderly	Abrysvo	FDA: May 2023, EU: August 2023	Q323
Moderna	Elderly	mRNA-1345	Submitted July 2023, expected H124	H224*
Johnson & Johnson	Elderly	discontinued	discontinued	discontinued
Bavarian Nordic	Elderly	discontinued	discontinued	discontinued

Maternal & Paediatric Segment

Company	Segment	Product	Approval	Launch
Pfizer	Maternal	Abrysvo	FDA: August 2023	H223
Moderna	Paediatric	mRNA-1345	H224*	H224*
Sanofi	Paediatric	SP-0125	2025*	2025*
Meissa	Paediatric	MV-102-968	2025*	2025*
Codagenix	Paediatric	CodaVax™-RSV	>2025*	>2025*

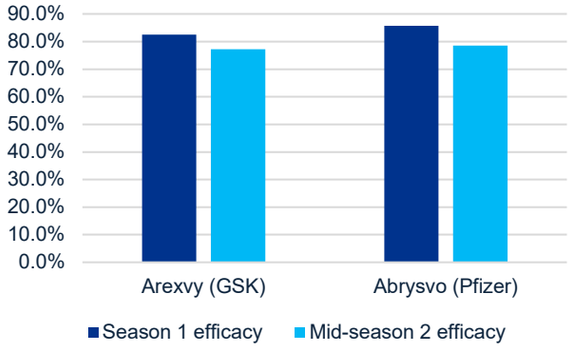
*Estimate based on publicly available data and timelines for approved RSV vaccines

There are opportunities to further optimise vaccine uptake through the collection of real-world data and awareness-raising. Manufacturers can further optimise the launches of RSV vaccines using the lessons learned from Covid-19 vaccines in terms of gaining strong real-world evidence which can be used to support discussions with health authorities in further markets. These efforts will need to be conducted in parallel with significant awareness-raising activities across both healthcare providers and the general public as awareness of RSV remains low compared with other respiratory viruses (15).

Discussions with payers will consider still unknown durability. Over late Q223 both GSK and Pfizer provided long-term data from their respective trials highlighting a modest (5.3%-7.1%) decline in efficacy in the second RSV season following vaccination compared with the first (16)(17). The magnitude of the decline was comparable across the products, failing to separate them in terms of efficacy. However, even a modest decline does raise the prospect of booster dosing which national vaccination schedules will need to evolve to account for, and which is likely to also be considered in pricing discussions.

Modest year-2 drop in efficacy noted across both products

Source: company press releases



Note: differences in trial design make cross product efficacy not directly comparable

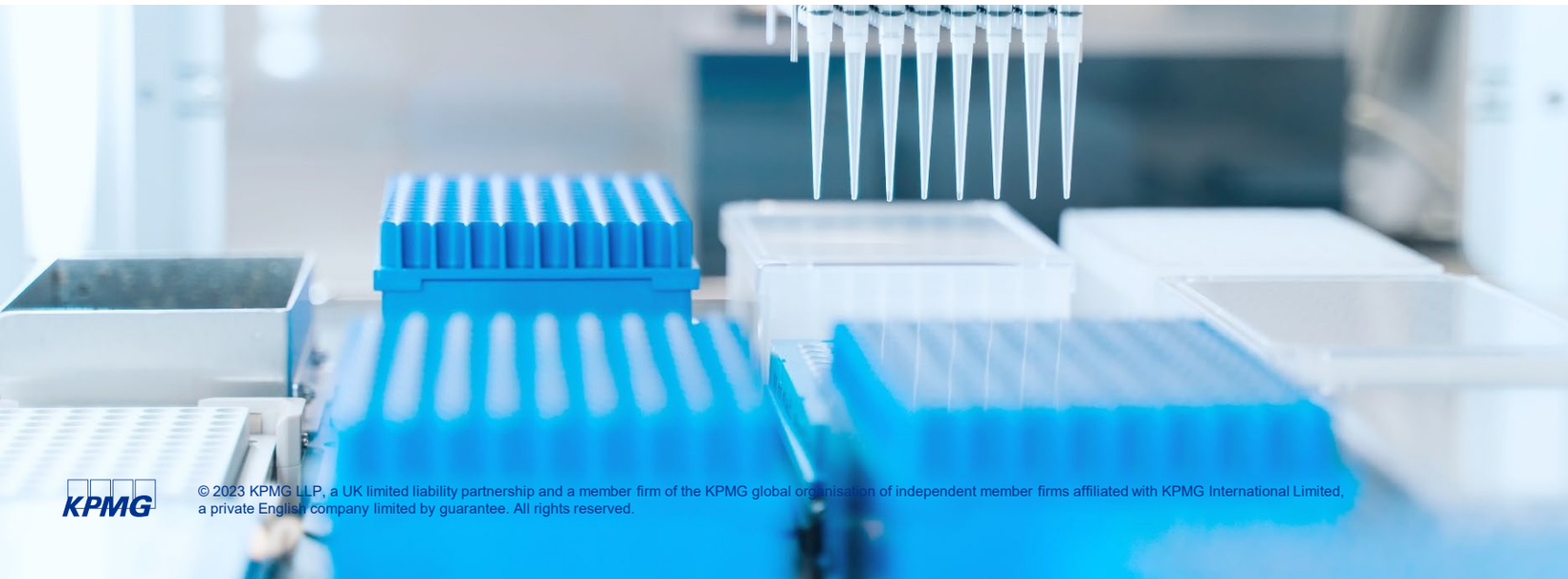
The development of combination vaccines could drive a further shift in the prevention of respiratory infection. Looking beyond the current wave of RSV vaccines, manufacturers are looking to build on the progress of these launches through the development of combination vaccines. Both Pfizer and Moderna are in the process of developing vaccines that combine an RSV vaccine with one or both of Covid-19 and influenza vaccines (18)(19). Icosavax is taking a different route – developing a combination vaccine for RSV and human metapneumovirus (hMPV) (14). These projects are still in early-to-mid-stage development across phases 2 and 1, however, have the potential to significantly reduce needle burden and capture a greater share of the combined markets.

Combination vaccines will consolidate respiratory virus prevention market

Source: company press releases

Company	Product	Combines	Phase
Pfizer	PF-07960613	RSV, Covid-19	2
Icosavax	IVX-A12	RSV, hMPV	2
Pfizer	PF-07941314	RSV, influenza	1
Moderna	mRNA-1230	RSV, Covid-19, influenza	1

We expect that prevention of respiratory viruses will remain a focus for manufacturers and for healthcare systems. Over the short-term this is likely to be centered around driving uptake of RSV, Covid-19, and influenza vaccines as these three continue to account for a significant amount of the additional Winter pressure on hospitals and HCPs. Over the longer term, we expect that the focus will shift to combination vaccines and other respiratory viruses that account for a significant burden on services. We expect that hMPV is likely to be one such virus that will draw focus.



Sources:

1. RSV Prevention Landscape: Opportunities & Challenges: https://www.linkedin.com/feed/update/urn:li:activity:7043540252233228288?utm_source=share&utm_medium=member_desktop
2. US FDA approves GSK's Arexvy, the world's first respiratory syncytial virus (RSV) vaccine for older adults: https://www.gsk.com/en-gb/media/press-releases/us-fda-approves-gsk-s-arexvy-the-world-s-first-respiratory-syncytial-virus-rsv-vaccine-for-older-adults/
3. U.S. FDA Approves ABRYSVO™, Pfizer's Vaccine for the Prevention of Respiratory Syncytial Virus (RSV) in Older Adults https://www.pfizer.com/news/press-release/press-release-detail/us-fda-approves-abrysvotm-pfizers-vaccine-prevention
4. Moderna Announces Global Regulatory Submissions For Its Respiratory Syncytial Virus (RSV) Vaccine, MRNA-1345: https://investors.modernatx.com/news/news-details/2023/Moderna-Announces-Global-Regulatory-Submissions-For-Its-Respiratory-Syncytial-Virus-RSV-Vaccine-MRNA-1345/default.aspx
5. Overview of respiratory virus epidemiology in the EU/EEA: https://erviss.org/
6. CDC Respiratory Disease Season Outlook: https://www.cdc.gov/forecast-outbreak-analytics/about/season-outlook.html
7. National Emergency Department Visits for COVID-19, Influenza, and Respiratory Syncytial Virus: https://www.cdc.gov/ncird/surveillance/respiratory-illnesses/index.html
8. GSK outpaces Pfizer in RSV vaccine market: https://www.biopharmadive.com/news/gsk-rsv-vaccine-sales-arexvy-third-quarter-pfizer/698446/#:~:text=Sales%20rose%2015%25%20year%20over,how%20much%20from%20pregnant%20women.
9. Seasonality of Respiratory Syncytial Virus — United States, 2017–2023: https://www.cdc.gov/mmwr/volumes/72/wr/mm7214a1.htm
10. Strong year-to-date and Q3 performance drives upgrade to full-year guidance: https://www.gsk.com/media/10667/q3-2023_31-october_final.pdf
11. Pfizer Reports Third-Quarter 2023 Results https://s28.q4cdn.com/781576035/files/doc_financials/2023/q3/Q3-2023-PFE-Earnings-Release.pdf
12. Johnson & Johnson halts development of RSV vaccine in midst of late-stage clinical trials: https://edition.cnn.com/2023/03/29/health/janssen-rsv-vaccine-trial/index.html
13. Bavarian Nordic to scrap RSV vaccine after study setback: https://www.biopharmadive.com/news/bavarian-nordic-rsv-vaccine-failure-discontinue-development/688724/#:~:text=Dive%20Brief%3A,of%20its%20Phase%203%20trial.
14. Biomedtracker: RSV Prevention Indication Report: BMT Respiratory Syncytial Virus (RSV) Prevention Indication Profile (biomedtracker.com)
15. Better awareness of RSV in older adults is needed to fight a growing burden: https://www.nature.com/articles/d41586-023-02958-y
16. GSK long-term data for Arexvy: GSK shares positive data for Arexvy, its respiratory syncytial virus (RSV) older adult vaccine, indicating protection over two RSV seasons | GSK
17. Pfizer long-term data for Abrysvo: Pfizer adult RSV vaccine efficacy declines slightly after 18 months (cnbc.com)
18. Pfizer pipeline: https://www.pfizer.com/science/drug-product-pipeline
19. Moderna pipeline: https://www.modernatx.com/research/product-pipeline

Contact:

Adrian Griffiths

Partner,
Head of Life Sciences

E: adrian.griffiths@kpmg.co.uk

T: +44 (0)7717 272 072

Fiona Thomas, MBChB

Chief Medical Officer

E: fiona.thomas1@kpmg.co.uk

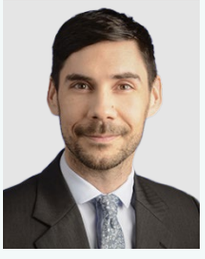
T: +44 (0)7510 375 989

Anna Marie Detert

Partner, Healthcare
and Life Sciences Strategy

E: annamarie.detert@kpmg.co.uk

T: +44 (0)7825 434 075



Guillaume Favier, PhD

Partner, Healthcare
and Life Sciences Strategy

E: guillaume.favier@kpmg.co.uk

T: +44 (0)7552 260 934

Beau Noafshar

Manager, Healthcare
and Life Sciences Strategy

E: beau.noafshar@kpmg.co.uk

T: +44 (0)7543 510 715

Some or all of the services described herein may not be permissible for KPMG audit clients and their affiliates or related entities.

kpmg.com/uk

Document Classification: KPMG Public

Create: CRT151909A | December 2023