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RSV Prevention Landscape

Opportunities and Challenges

2023

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2023 will be a pivotal year for the respiratory syncytial virus (RSV) prevention landscape with the potential launch of four products across infant and elderly indications.

RSV accounts for around 3 million hospitalisations and 120,000 deaths globally each year, with around 50% of these hospitalisations in infants.[1] The burden on healthcare systems is therefore significant, even before we consider the broader societal impact of loss of productivity by carers. There is some light on the horizon however with these figures expected to be reduced drastically over the coming years as multiple new products approach the market. Manufacturers aim to commercialise these products as early as the Winter 2023 RSV season; vaccines from three manufacturers (GSK, Pfizer and Moderna) will compete to address the significant unmet medical need in elderly patients.[2] Meanwhile in the smaller paediatric segment, Sanofi and AstraZeneca's alliance antibody for infants (Beyfortus (nirsevimab)) will compete against Pfizer's maternal RSV vaccine.[3]

Prevention products expected across elderly, maternal and infant indications: products with Phase III data reported in last 12 months

Source: company press releases

Company	Product	Segment	Phase III results reported
Pfizer	RSVPreF	Elderly	Aug-22
GSK	GSK3844766A	Elderly	Jun-22
Moderna	mRNA-1345	Elderly	Jan-23
AstraZeneca	Beyfortus	Infants	Mar-22
Pfizer	RSVPreF	Maternal	Nov-22

Note:

1 Eugenio Baraldi, Giovanni Checcucci Lisi, Claudio Costantino, Jon H. Heinrichs, Paolo Manzoni, Matteo Riccò, Michelle Roberts & Natalya Vassilouthis (2022) RSV disease in infants and young children: Can we see a brighter future?, Human Vaccines & Immunotherapeutics, 18:4, DOI: 10.1080/21645515.2022.2079322

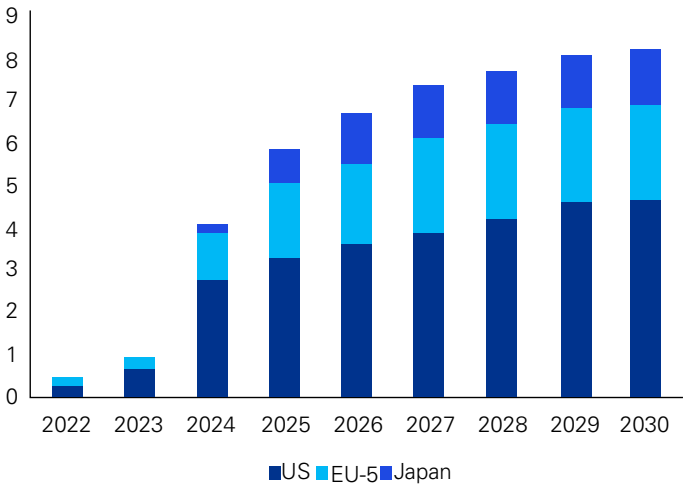
2 Company press releases: Pfizer, GSK, Moderna

3 Citeline Disease Analysis: Respiratory Syncytial Virus (RSV) Prevention Disease Analysis: Respiratory Syncytial Virus (RSV) Prevention | Research & Analysis | Datamonitor Healthcare

Beyond the 2023/24 season, further products from Bavarian Nordic and Johnson & Johnson will continue to shake up the elderly market. Two infant vaccines are currently in Phase II development from Sanofi and Meissa whilst combination vaccines (combining RSV, influenza and Covid-19) could pose an attractive solution to the increasing needle burden and overall administration costs for elderly adult programmes.[3] The combined effect of these products will see the size of the market swell to over USD8bn by 2030 across US, Japan & EU-5 pharmaceutical markets.[4] Below we highlight some the challenges that manufacturers will need to tackle to maximise the launch of novel RSV prevention products.

RSV prevention market expected to swell over period to 2030: RSV prevention sales forecast across major markets (USDbn)

Source: Citeline

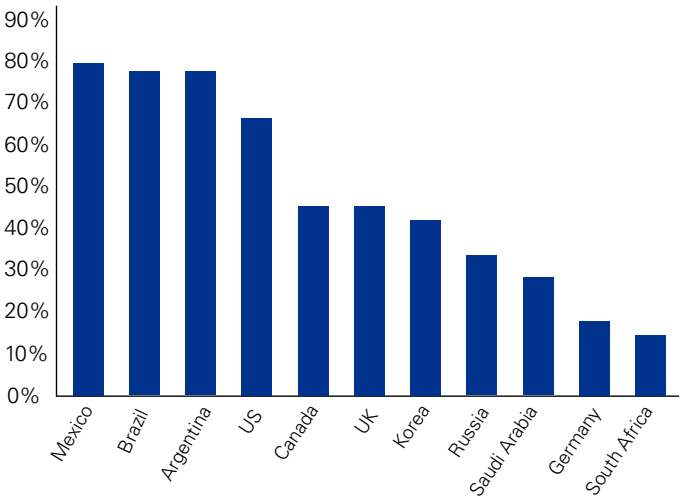


Vaccine hesitancy will act as a barrier to market growth

Uptake of vaccines varies significantly by population group and by market. Current levels of awareness around the risk and potential impact of RSV across HCPs and the general public is generally low and will require significant efforts from both manufacturers and healthcare systems via large scale disease awareness campaigns. Within the older adult segment, vaccine fatigue may also be an issue, as individuals in this group could be facing the prospect of at least 3 annual vaccinations (Covid-19, RSV and influenza), with this burden leading to hesitancy towards a new RSV vaccine, particularly in markets where initial confidence in vaccines is lower (see chart below). For maternal vaccines, hesitancy may be particularly acute; as highlighted by data from the WHO below, uptake for maternal influenza vaccine remains highly variable. Safety concerns are a well-established barrier to uptake of maternal immunization; 7%-52% of unvaccinated women gave safety concerns as a reason.[5] Uptake for infants could also be a challenge but in our view to a lesser extent than the first two segments; this is based on historical vaccination coverage rates for routine childhood vaccines which tend to be higher than for vaccines across other groups.[6]

Vaccination uptake varies significantly by market and segment: Vaccine coverage (%) of influenza vaccine in pregnant women, 2020

Source: Airfinity, WHO



Note:

3 Citeline Disease Analysis: Respiratory Syncytial Virus (RSV Prevention Disease Analysis: Respiratory Syncytial Virus (RSV) Prevention | Research & Analysis | Datamonitor Healthcare

4 Citeline RSV Patient-Based Forecast Model

5 Qiu X, Bailey H and Thorne C (2021) Barriers and Facilitators Associate With Vaccine Acceptance and Uptake Among Pregnant Women in High Income Countries: A Mini-Review. Front. Immunol. 12:626717. doi:10.3389/fimmu.2021.626717

6 WHO: Pneumococcal vaccination coverage (who.int)

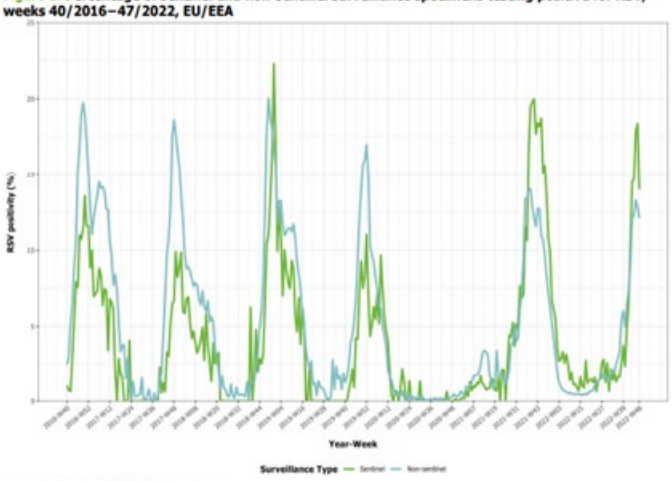
Disrupted seasonality impacts attractiveness to healthcare systems.

Surveillance data from 15 European countries demonstrates that RSV generally presents a clear annual seasonality from October to March that varies slightly across Europe depending on climate. This pattern was disrupted by non-pharmaceutical interventions used by governments during the Covid-19 pandemic with no clear seasonal spike in Winter 2020, delayed peaks in Spring 2021 and a plateau over early spring to mid-summer.[7] The potential for continued disrupted seasonality in 2023 and beyond means that healthcare systems will struggle to have certainty on the timing of the start of the 2023 RSV season. This in turn could complicate annual dosing strategies for prophylaxis.

Disrupted seasonality could persist: Percentage of specimens testing positive for RSV, weeks 40/2016–47/2022, EU/EEA (%)

Source: ECDC

Figure 1. **Percentage of sentinel and non-sentinel surveillance specimens testing positive for RSV, weeks 40/2016–47/2022, EU/EEA**



Source: TESSy, INFLVIRWAGGR record type

Note:

7 European Centre For Disease Prevention And Control (ECDC): https://www.ecdc.europa.eu/en/publications-data/intensified-circulation-respiratory-syncytial-virus-rsv-and-associated-hospital

Strong need for real world evidence.

We expect that the early Covid-19 market could act as a good model for RSV prevention with multiple new competitors launched within a short space of time. In that situation real world evidence proved invaluable with Pfizer leveraging early evidence for Comirnaty in Israel to win government tenders and establish its position in the marketplace.[8] Similarly, companies should look to make sure platforms are in place to ensure robust epidemiological surveillance to then use this in tracking vaccine effectiveness post-launch in support of reimbursement negotiations. These platforms can subsequently be used to demonstrate durability of protection and test any potential changes to the dosing schedule.

Durability of protection is still unknown.

Efficacy data provided by GSK and Pfizer to date covers RSV season for 2021-22 which was characterised by lower infections, likely caused by disrupted seasonality due to Covid-19 as discussed above. Both trials have continued to run for the 2022-23 season which has seen a more typical trajectory in terms of total numbers of RSV infections, therefore, data from this period, which is expected in Q2 23, could be crucial in differentiating the products and for pricing. We expect continued efficacy over the second season given data from J&J's Phase IIb CYPRESS trial which shows only a minor drop in efficacy when examining over two seasons (78.7%) compared to just one (80.0%).[9] As durability evidence is updated over the long-term, we expect that national vaccination schedules will evolve to account for this.

Note:

8 https://www.pfizer.com/news/press-release/press-release-detail/ral-world-evidence-confirms-high-effectiveness-pfizer

This comprehensive real-world evidence can be of importance to countries around the world as they advance their own vaccination campaigns one year after the World Health Organization (WHO) declared COVID-19 a pandemic.

9 Johnson & Johnson; https://www.jnj.com/janssen-announces-phase-2b-data-demonstrating-its-investigational-rsv-adult-vaccine-provided-80-protection-against-lower-respiratory-infections-in-older-adults

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