## IPCRG practice driven answers on COVID-19 and respiratory questions





# When can we expect the Respiratory Syncytial Virus (RSV) vaccine to be approved and available?

### What the research says

Several vaccines against respiratory Syncytial Virus (RSV) are in development and at least two are in the final stages of clinical testing and will undergo priority review by the US Food and Drug Administration (FDA) (GSK November 2022; Pfizer December 2022). If successful, the first approval could be granted in May 2023 for use in the US. Phase 3 trials have been completed in adults over the age of 60 years and it's likely that the vaccines will first be approved for use in this age group (GSK October 2022; Pfizer August 2022). A Phase 3 trial for a vaccine to be given to pregnant women reported in November 2022 with 82% efficacy against severe RSV for infants from birth to 90 days and 70% through to 6 months (Pfizer November 2022). Timelines for approval of this vaccine are not vet available.

RSV is a common seasonal virus that causes lower respiratory tract infection. The virus tends to cause most infections in the late autumn and early winter months. While most RSV infections are mild and self-limiting, severe illness with need for hospitalisation may occur following infection, particularly in

vulnerable groups including the very old and the very young. Severe illness can also occur in healthy adults and infants with no risk factors. There are no specific treatments for RSV infection and this means that vaccination is critical to drive a reduction in cases and consequently in severe infections. In older adults, risk for severe disease is due to agerelated decline in immunity. Chronic conditions, including those affecting the respiratory system, also increase the risk of severe infections. In infants, the greatest risk for severe disease is during the first months of life and is greatest in preterm babies and those with congenital heart or lung disease.

## What this means for your clinical practice

- There are currently no approved vaccines against RSV for use in adults
- For people concerned about RSV, advise that clinical trials are underway and if successful the first vaccines could approved for use in the US in 2023 for adults and pregnant women

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#### Supporting references

GSK. GSK's older adult respiratory syncytial virus (GSK) vaccine candidate shows 94.1% reduction in severe RSV disease and overall vaccine efficacy of 82.6% in pivotal trial. 13 October 2022. Available at:

https://www.gsk.com/en-gb/media/press-releases/gsk-s-older-adult-respiratory-syncytial-virus-rsv-vaccine-candidate/. Accessed January 2023.

GSK. GSK's respiratory syncytial virus older adult vaccine candidate granted priority review by US FDA. 2 November 2022. Available at: <a href="https://us.gsk.com/en-us/media/press-releases/gsk-s-rsv-oa-vaccine-candidate-granted-priority-review-by-us-fda/">https://us.gsk.com/en-us/media/press-releases/gsk-s-rsv-oa-vaccine-candidate-granted-priority-review-by-us-fda/</a>. Accessed January 2023.

Pfizer. Pfizer announces positive top-line data from Phase 3 trial of older adults for its bivalent respiratory syncytial virus (RSV) vaccine candidate. 25 August 2022. Available at:

https://investors.pfizer.com/Investors/News/news-details/2022/Pfizer-Announces-Positive-Top-Line-Data-from-Phase-3-Trial-of-Older-Adults-for-its-Bivalent-Respiratory-Syncytial-Virus-RSV-Vaccine-Candidate/default.aspx. Accessed January 2023.

Pfizer. Data of Phase 3 Global maternal immunization trial for its bivalent respiratory syncytial virus (RSV) vaccine candidate. 1 November 2022. Available at: <a href="https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-positive-top-line-data-phase-3-global">https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-positive-top-line-data-phase-3-global</a>. Accessed January 2023.

Pfizer. US FDA accepts for priority review the biologics license application for Pfizer's respiratory syncytial virus vaccine candidate for the prevention of RSV disease in older adults. 7 December 2022. Available at: <a href="https://www.pfizer.com/news/press-release/press-release-detail/us-fda-accepts-priority-review-biologics-license-0">https://www.pfizer.com/news/press-release-detail/us-fda-accepts-priority-review-biologics-license-0</a>. Accessed January 2023.

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