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US FDA accepts application to review expanded use of GSK's RSV vaccine, Arexvy, for adults 18-49 at increased risk

- More than 21 million US adults under the age of 50 have at least one risk factor for severe RSV infection¹
 - Submission supported by positive Phase IIIb data showing immune response and safety results in this population
 - FDA decision anticipated H1 2026
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GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has accepted for review an application to extend the indication of Arexvy (respiratory syncytial virus (RSV) vaccine, adjuvanted) to adults aged 18-49 who are at increased risk. GSK's RSV vaccine is approved in the US for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged 60 and older, and for those aged 50-59 years who are at increased risk.

RSV is a common contagious virus affecting the lungs and breathing passages and impacts an estimated 64 million people of all ages globally every year.² More than 125 million adults in the US are under 50 years of age.¹ An estimated 21 million of these people have at least one diagnosed risk factor for severe RSV infection, such as chronic obstructive pulmonary disease (COPD), asthma, congestive heart failure and coronary heart disease (CHD).¹ RSV can exacerbate certain medical conditions and can also lead to severe illness resulting in hospitalisation, and even death.^{3 4 5}

This regulatory submission is supported by a phase IIIb trial evaluating immune response and safety in adults aged 18-49 at increased risk compared to adults aged 60 and above.⁶ The safety and reactogenicity data were consistent with results from the phase III programme that supported the initial approval of the vaccine in the US.

A regulatory decision by the FDA on this submission is expected in H1 2026.

GSK is continuing to seek expanded indications for its RSV vaccine in other geographies including in the European Economic Area and Japan.

About GSK's RSV vaccine

Respiratory Syncytial Virus Vaccine, Adjuvanted, contains recombinant RSV glycoprotein F stabilised in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary AS01E adjuvant.

The FDA has approved GSK's RSV vaccine for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older, and those aged 50-59 who are at increased risk. The use of this vaccine should be in accordance with official recommendations. As with any vaccine, a protective immune response may not be elicited in all vaccinees.

The vaccine has been approved for the prevention of RSV-LRTD in individuals 60 years of age and older in more than 60 countries. In addition, it is approved for use in individuals aged 50-59 who are at increased risk in more than 50 markets, including the US, Japan and Europe.

Please refer to the full US Prescribing Information (PI) for important dosage, administration, and safety information:
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Arexvy/pdf/AREXVY.PDF

The AS01 adjuvant system, owned by GSK, includes the QS-21 adjuvant, licensed by Antigenics, a wholly owned subsidiary of Aenus.

About the NCT06389487 trial

NCT06389487 is a phase IIIb open-label study to evaluate the non-inferiority of the immune response and to evaluate the safety of GSK's RSV vaccine in adults aged 18-49 at increased risk for RSV disease (n=426) compared to adults aged 60 and older (n=429). An additional cohort of 603 participants aged 18-49 were followed up for adverse events separate to safety follow up of the initial cohort. 1,458 participants were enrolled across 52 locations in 6 countries, including 16 US sites.

The trial's co-primary endpoints were RSV-A and RSV-B neutralisation titres expressed as geometric mean titre ratio (relative to older adults over adults at increased risk) and seroresponse rate in RSV-A and RSV-B neutralising titres one month post vaccine administration. There were also safety and immunogenicity secondary endpoints.

About RSV in adults

RSV is a common contagious virus affecting the lungs and breathing passages and impacts an estimated 64 million people of all ages globally every year.² Adults can be at increased risk for RSV disease due to certain comorbidities, immune compromised status, or advanced age.⁵ RSV can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death.⁵

About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at [gsk.com](https://www.gsk.com).

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Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q1 Results for 2025.

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Note:

Among adults aged 20-49 years in the US, a total of 17.0% (N=21 million/125 million) had at least one diagnosed risk factor for severe RSV disease (including congestive heart failure, coronary heart disease, stroke, angina, myocardial infarction, chronic obstructive pulmonary disease, current asthma, diabetes, current liver disease, and/or renal disease)

References:

1. E.Horn et al, "Characteristics Associated with the Presence of One or More Risk Factors for Severe Respiratory Syncytial Virus Disease among Adults in the United States", poster presented at ID Week 2024 [available on demand: P691 - [DV-009542.pdf](#)]
2. National Institute of Allergy and Infectious Diseases, Respiratory Syncytial Virus (RSV). Available at: <https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv> Accessed June 2025
3. McLaughlin JM, Khan F, Begier E, et al. Rates of Medically Attended RSV Among US Adults: A Systematic Review and Meta-analysis. *Open Forum Infect Dis*.
4. Atamna A, Babich T, et al. Morbidity and mortality of respiratory syncytial virus infection in hospitalized adults: Comparison with seasonal influenza. *Int J Infect Dis*. 2021 Feb;103:489-493. doi: [10.1016/j.ijid.2020.11.185](#).
5. Falsey, AR et al. Respiratory syncytial virus infection in elderly and high-risk adults, in *New Engl J Med* 2005; 352:1749-59. doi: [10.1056/NEJMba043951](#)
6. Clinicaltrials.gov, "A Study on the Immune Response and Safety of Vaccine Against Respiratory Syncytial Virus (RSV) Given to Adults 18 to 49 Years of Age at Increased Risk for Respiratory Syncytial Virus Disease, Compared to Older Adults 60 Years of Age and Above" - available at: <https://clinicaltrials.gov/study/NCT06389487>

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