Stock-exchange announcement
For media and investors only

Issued: March 13, 2026, Philadelphia, PA

GSK's RSV vaccine, AREXVY, approved in US for expanded age indication in adults aged 18–49 years at increased risk

- In the US, an estimated 21 million adults under 50 have at least one risk factor for severe RSV infection[1]*

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has expanded the approved age indication of AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) to adults aged 18 to 49 years at increased risk for lower respiratory tract disease (LRTD) caused by RSV. AREXVY was previously approved in the US for the prevention of RSV-related LRTD in adults aged 60 and older, and adults aged 50–59 at increased risk for LRTD caused by RSV. This vaccine is not for use in pregnant individuals.

Sanjay Gurunathan, GSK Head of Vaccines and Infectious Diseases Research and Development, said: "This age expansion can help address a significant medical need for adults in the United States at higher risk of severe RSV disease due to certain underlying conditions, and help ease pressure on the healthcare system. We are proud of this latest step in our strategy to bring RSV prevention to broader adult populations."

The annual RSV burden among US adults aged 18–49 years is about 17,000 hospitalizations, 277,000 emergency department admissions, and 1.97 million outpatient visits.[2†] Most hospitalizations in younger adults occur in those with chronic medical conditions which place them at increased risk for severe RSV disease (e.g. chronic cardiopulmonary, kidney or renal disease, obesity and diabetes).[2†]

The FDA's decision was supported by data from a Phase IIIb trial (NCT06389487) demonstrating a non-inferior immune response compared to adults aged 60 years and above.[3] Vaccine efficacy was demonstrated in the earlier Phase III trial (NCT04886596).[4] The safety profile was consistent with findings from the broader Phase III program that supported the initial US approval, with the most common adverse events being injection site pain, fatigue, myalgia, headache, and arthralgia within four days of vaccination.[3]

GSK continues to advance regulatory submissions for its RSV vaccine across multiple geographies to expand availability and support long-term growth objectives.

About AREXVY

AREXVY contains recombinant RSV glycoprotein F stabilised in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary AS01$_E$ adjuvant before administration.

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 70 countries. In addition, it is approved for use in individuals aged 50–59 who are at increased risk due to certain underlying medical conditions in more than 60 countries. In the European Economic Area it is approved for adults aged 18 years and older.

The GSK proprietary AS01 adjuvant system contains STIMULON QS-21 adjuvant licensed from Antigenics LLC, a wholly owned subsidiary of Agenus Inc. STIMULON is a trademark of SaponiQx Inc., a subsidiary of Agenus.

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

About the NCT06389487 trial

NCT06389487 is a Phase IIIb, open-label multi-country immunogenicity trial to evaluate the non-inferiority of the immune response and evaluate safety in participants aged 18–49 at increased risk for lower respiratory tract disease (LRTD) caused by RSV (n=426), compared to participants aged 60 years and above (n=429) after a single dose of GSK's RSV vaccine. An additional cohort of 603 participants aged 18–49 was followed up for adverse events separate to safety follow up of the initial cohort. A total of 1,458 participants were enrolled across 52 locations in six countries, including 16 US sites.

The study assessed the immune response in participants aged 18–49 with pre-defined stable chronic diseases leading to an increased risk for RSV disease, compared to those aged 60 years and above. The trial's primary endpoints were RSV-A and RSV-B neutralization titres of adults aged 18–49 years at one month after the vaccine administration compared to adults aged 60 and older. There were also safety and immunogenicity secondary and tertiary endpoints. Safety and reactogenicity data were consistent with results from the initial data read out in NCT04886596. The most common local adverse event was pain. The most common systemic adverse events were myalgia, fatigue and headache, which were largely transient and mild to moderate in intensity.

Indication for AREXVY

AREXVY is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in:

- individuals 60 years of age and older;
- individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

Limitations of Use

AREXVY is not for use in pregnant individuals.

Important Safety Information for AREXVY

- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of AREXVY
- The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination with AREXVY
- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of AREXVY
- Syncope (fainting) may occur in association with administration of injectable vaccines, including AREXVY. Procedures should be in place to avoid injury from fainting
- Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to AREXVY
- In adults 60 years of age and older, the most commonly reported adverse reactions (≥10%) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%)
- In adults 50 through 59 years of age, the most commonly reported adverse reactions (≥10%) were injection site pain (75.8%), fatigue (39.8%), myalgia (35.6%), headache (31.7%), arthralgia (23.4%), erythema (13.2%), and swelling (10.4%)
- In adults 18 through 49 years of age, the most commonly reported adverse reactions (≥10%) were injection site pain (76.0%), myalgia (59.9%), fatigue (59.6%), headache (43.6%), and arthralgia (28.3%)
- Vaccination with AREXVY may not result in protection of all vaccine recipients

Please see full Prescribing Information for AREXVY.

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.[5] Adults can be at increased risk for RSV disease due to certain comorbidities, immune compromised status, or advanced age.[6] RSV can exacerbate certain conditions, including chronic obstructive pulmonary disease (COPD), asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalization, and death.[6] Compared to children, adults hospitalized for RSV are at a higher risk of severe complications, require more costly treatments, have a higher fatality rate, and the true number of RSV-related cases is likely underestimated due to lack of routine testing.[7,8,9,10]

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 www.gsk.com.

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Footnotes
* Self-reported diagnoses of risk factors collected via the National Health and Nutrition Examination Survey (NHANES) in US adults 20-49 years of age. The figure of 21.3 million is based on 17.0% of a total 125,255,765 adults 20–49 who had at least one risk factor (including congestive heart failure, coronary heart disease, stroke, angina, myocardial infarction, chronic obstructive pulmonary disease, asthma, diabetes, liver disease and/or renal disease) for severe RSV disease

† Based on a systematic review and meta-analysis of studies describing population-based rates of medically attended RSV among US adults (n=14 articles published between 2007 and 2021). Estimates were based on RSV as detected by RT-PCR of NP or nasal swabs and then adjusted for under detection. Age-specific US census population estimates were applied to project the expected number of annual cases.

References:

[1] 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] McLaughlin JM, et al. Rates of Medically Attended RSV Among US Adults: A Systematic Review and Meta-analysis. Page 17 Supplementary Data. Open Forum Infect Dis. 2022 Jun 17;9(7):ofac300. doi: 10.1093/ofid/ofac300. PMID: 35873302; PMCID: PMC9301578.
[3] 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. Last accessed: March 2026.
[4] Clinicaltrials.gov. Efficacy Study of GSK's Investigational Respiratory Syncytial Virus (RSV) Vaccine in Adults Aged 60 Years and Above. Available at: https://clinicaltrials.gov/study/NCT04886596. Last accessed: March 2026.
[5] National Institute of Allergy and Infectious Diseases, Respiratory Syncytial Virus (RSV). Available at: https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv. Last accessed: March 2026.
[6] Falsey, A, R *et al.* Respiratory syncytial virus infection in elderly and high-risk adults, in *New Engl J Med* 2005; 352:1749-59. doi: 10.1056/NEJMoa043951.
[7] Alfano F, *et al*. Respiratory Syncytial Virus Infection in Older Adults: An Update. *Drugs Aging.* 2014;41:487–505.
[8] Niekler P, *et al*. Hospitalizations due to respiratory syncytial virus (RSV) infections in Germany: a nationwide clinical and direct cost data analysis (2010–2019). *Infection*. 2024;52(5):1715–1724.
[9] Günen H, *et al*. Key Challenges to Understanding the Burden of Respiratory Syncytial Virus in Older Adults in Southeast Asia, the Middle East, and North Africa: An Expert Perspective. *Adv Ther.* 2024;41(11):4312–4334.
[10] Grace M, *et al*. Economic burden of respiratory syncytial virus infection in adults: a systematic literature review. *J Med Econ*. 2023;26(1):742–759.