Stock-exchange announcement
For media and investors only

Issued: July 14, 2025, Philadelphia, PA

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 (respiratory syncytial virus) infection[1]
- Submission supported by positive phase IIIb data showing immune response and safety results in this population
- FDA decision anticipated H1 2026

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 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 for LRTD caused by RSV.

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 hospitalization, 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 program 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 stabilized in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary AS01$_E$ 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 Agenus.

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 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

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%)
- There are no data on the use of AREXVY in pregnant or breastfeeding individuals. AREXVY is not approved for use in persons <50 years of age
- Vaccination with AREXVY may not result in protection of all vaccine recipients

Please see full Prescribing Information for AREXVY.

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 neutralization titers expressed as geometric mean titer ratio (relative to older adults over adults at increased risk) and seroresponse rate in RSV-A and RSV-B neutralizing 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, hospitalization, 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.

Stock-exchange announcement
For media and investors only

GSK enquiries

Media:	Simon Steel	+44 (0) 20 8047 5502	(London)
	Simon Moore	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Constantin Fest	+44 (0) 7831 826525	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

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.

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

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/NEJMoa043951
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