US FDA approves expanded age indication for GSK’s **Arexvy**, the first respiratory syncytial virus (RSV) vaccine for adults aged 50-59 at increased risk

- Over 13 million US adults aged 50-59 years have a medical condition that increases their risk of severe RSV outcomes
- Clinical development programme continues to evaluate safety and immunogenicity in adults 18+ with data read-outs expected H2 2024
About GSK’s RSV vaccine
Respiratory Syncytial Virus Vaccine, Adjuvanted, contains recombinant RSV glycoprotein F stabilised in theprefusion conformation (RSVPreF3). This antigen is combined with GSK’s proprietary AS01e adjuvant.

In May 2023, the FDA 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. 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 also been approved for the prevention of RSV-LRTD in individuals 60 years of age and older in over 40 countries, including Europe, Japan and US. Regulatory reviews in multiple countries are ongoing. The proposed trade name remains subject to regulatory approval in other markets.

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

About the NCT05590403 trial
NCT05590403 is a phase III, placebo-controlled, observer-blind, randomised, multi-country immunogenicity trial to evaluate the non-inferiority of the immune response and evaluate safety in participants aged 50 to 59, including those at increased risk for RSV-LRTD compared to older adults aged 60 years and above after a single dose of GSK’s RSV vaccine.

The study assessed the immune response in participants aged 50 to 59 with pre-defined stable chronic diseases leading to an increased risk for RSV disease (n=570). Immune responses in a broader group of participants aged 50-59 years without these pre-defined chronic diseases (n=570) were also evaluated compared to adults aged 60 and older. The trial’s primary endpoints were RSV-A and RSV-B neutralisation titres of both groups 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 AReSVi-006 data read out. The most common local adverse event was pain. The most common systematic adverse events were myalgia, fatigue and headache, which were largely transient and mild to moderate in intensity.

Results from this trial have been presented at the ACIP meeting of October 2023 and at ReSVinet in February 2024, and have been submitted for peer-reviewed publication. The data are being submitted to other regulators to support potential label expansions.

About RSV in adults
RSV is a common contagious virus affecting the lungs and breathing passages. Adults can be at increased risk for RSV disease due to comorbidities, immune compromised status, or advanced age.4 RSV can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death.4 Each year, RSV is estimated to cause approximately 177,000 hospitalisations in adults 65 years and older4 and 42,000 in adults aged 50-64 years old in the US2.

Please see the full US Prescribing Information:
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Arexvy/pdf/AREXVY.PDF

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.

GSK enquiries
Media: Tim Foley +44 (0) 20 8047 5502 (London)
Simon Moore +44 (0) 20 8047 5502 (London)
Kathleen Quinn +1 202 603 5003 (Washington DC)
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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 under Item 3.D “Risk factors” in GSK’s Annual Report on Form 20-F for 2023, and GSK’s Q1 Results for 2024.

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No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

References

2 McLaughlin JM et al, “Rates of Medically Attended RSV Among US Adults: A Systematic Review and Meta-analysis” in Open Forum Infectious Diseases, Volume 9, Issue 7, July 2022
4 Centers for Disease Control and Prevention (CDC), RSV in Older Adults and Adults with Chronic Medical Conditions, 2024
5 ClinicalTrials.gov, A Study on the Immune Response and Safety of a Vaccine Against Respiratory Syncytial Virus Given to Adults 50-59 Years of Age, Including Adults at Increased Risk of Respiratory Syncytial Virus Lower Respiratory Tract Disease, Compared to Older Adults 60 Years of Age and Above 2023. NCT05590403.