GSK

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For media and investors only

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New data for *Arexvy*, GSK's respiratory syncytial virus vaccine, show potential to help protect a broader group of adults at increased risk for RSV disease

- Single dose of vaccine elicited robust immune response with acceptable safety profile in adults aged 18-49 at increased risk for RSV-LRTD
- Two doses of vaccine in immunocompromised adults aged 18 and above elicited immune responses similar to one dose in healthy adults aged 50+ and with an acceptable safety profile
- In the US alone, adults aged 18-49 with at least one risk factor for RSV disease could exceed 21 million[1]

GSK plc (LSE/NYSE: GSK) today announced new preliminary data for *Arexvy* (respiratory syncytial virus vaccine, recombinant adjuvanted) in adults aged 18-49 at increased risk for RSV-LRTD due to certain underlying medical conditions and in adults who are immunocompromised. These data show the vaccine's potential to help protect a broader group of adults at risk from the potentially serious consequences of RSV. In the US alone, the number of adults aged 18-49 with at least one risk factor that could put them at risk for RSV disease could exceed 21 million.[1]

The vaccine is currently approved for use in adults aged 60 and above in over 50 countries, and in adults aged 50-59 at increased risk in a number of countries including the US and Europe*. There are currently no RSV vaccines recommended for adults younger than 60 years of age who are at increased risk for RSV disease, despite the burden of disease in this population.

Tony Wood, Chief Scientific Officer, GSK, said: "These promising data add to the evidence supporting GSK's RSV vaccine and could help expand protection to more adults at risk from RSV disease. They also provide valuable insights into the potential impact of a second dose for certain populations. We're committed to working with health authorities and regulators to help adults at increased risk of RSV disease benefit from vaccination."

In the phase IIIb trial (NCT06389487[2]) a single dose of the vaccine elicited robust immune responses in adults aged 18-49 at increased risk for RSV-LRTD due to certain underlying medical conditions (n=395). The immune response was non-inferior to that observed in adults aged 60 and above (n=417), meeting the trial's co-primary endpoints.

In the phase IIb trial (NCT05921903[3]) a single dose of the vaccine showed a robust immune response in adults aged 18 and above who are immunocompromised due to kidney or lung transplant (n=131), with a second dose (n=130) eliciting responses similar to those of healthy adults aged 50 and older who received one dose (n=125). These immune responses were consistent for RSV-A and RSV-B subtypes in all groups (those who received 1 or 2 doses). These data will be presented today at the meeting of the CDC's Advisory Committee on Immunization Practices.

In both studies, the safety and reactogenicity data were consistent with results from the phase III programme that have supported the initial approval of the vaccine. The most common local adverse event was pain, and most common systematic adverse events were fatigue, myalgia, arthralgia and headache, most of which were transient and mild in intensity.

RSV is a common, contagious virus that can cause severe respiratory illness and impacts an estimated 64 million people of all ages globally every year.[4] Immunocompromised people and those with certain underlying medical conditions, such as chronic obstructive pulmonary disease (COPD), asthma, heart failure and diabetes are at increased risk for severe consequences from an RSV infection compared to those without these conditions,[5, 6] including having a higher risk of mortality.[7]

Final results from these trials will be presented at upcoming medical conferences and submitted for peer-reviewed publication. The final data will also be submitted to the US Food and Drug Administration (FDA) and other regulators to support potential label updates.

About the trial designs

NCT06389487 is a phase IIIb open-label study to evaluate the non-inferiority of the immune response and to evaluate the safety of the GSK's RSV vaccine in adults aged 18-49 at increased risk for RSV disease (n=395) compared to adults aged 60 and older (n=417). 1,457 participants were enrolled across 52 locations in 6 countries.

The trial's co-primary endpoints were RSV-A and RSV-B neutralisation titers expressed as mean geometric titer ratio (relative to older adults over adults at increased risk) and sero-response in RSV-A and RSV-B neutralising titers one month post vaccine administration. There were also safety and immunogenicity secondary endpoints. An additional cohort of 601 participants aged 18-49 were followed up for adverse events separate to safety follow up of the initial cohort. The study is ongoing to collect further safety and immunogenicity data up to 6 months post vaccination and is expected to finish in 2025.

NCT05921903 is a phase IIb, randomized, controlled, open-label, multi-country study to evaluate the immune response and safety of GSK's RSV vaccine in adults (≥18 years of age) who are immunocompromised due to lung and renal transplant, comparing 1 versus 2 doses (1 dose, n=131, 2 doses, n=130) one month (30-42 days) after the second vaccine administration compared to a control group of non-immunocompromised adults aged 50 and above receiving a single dose of GSK's RSV vaccine (n=125 non-immunocompromised adults aged 50 and above). 386 participants were enrolled across 48 locations in 8 countries.

The trial's co-primary endpoints were RSV-A and RSV-B neutralisation titers following a first and a second dose of GSK's RSV vaccine expressed as mean geometric increase post dose 2 relative to post dose 1 at approximatively one month. There were also safety and immunogenicity secondary endpoints. The study is ongoing to collect further safety and immunogenicity data up to 12 months post last dose and is expected to finish in 2025.

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 AS01$_E$ adjuvant.

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 50 countries, including Europe, Japan and US. In addition, it is approved in the US and EU/EEA countries for use in individuals aged 50-59 who are at increased risk due to certain underlying medical conditions. Regulatory reviews for this extended indication are also undergoing review in other countries – including Japan. 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 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.

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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)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Annabel Brownrigg-Gleeson	+44 (0) 7901 101944	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(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 under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q2 Results for 2024.

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

Notes:
* European Union member states, as well as in the European Economic Area (EEA) countries Iceland, Norway and Liechtenstein.

References

[1] Based on a study focusing on US adults aged 20-49. 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 CHF, CHD, stroke, angina, MI, COPD, current asthma, diabetes, current liver disease, and/or renal disease) – in 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 poster [available on demand: P691 - https://idweek2024.eventscribe.net/index.asp]
[2] 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
[3] Clinicaltrials.gov, "A Study on the Immune Response and Safety of an RSV Vaccine When Given to Adults 18 Years of Age and Above Who Received Lung or Kidney Transplant and Are at an Increased Risk of Respiratory Syncytial Virus Lower Respiratory Tract Disease and Compared to Healthy Adults 50 Years of Age and Above (RSV OA=ADJ-023)" – available at: https://clinicaltrials.gov/study/NCT05921903
[4] 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: September 2024
[5] Branche AR et al., Incidence of Respiratory Syncytial Virus Infection Among Hospitalized Adults, 2017–2020 in *Clinical Infectious Diseases*, 2022:74:1004–1011
[6] CDC, Clinical overview of RSV. Available at: https://www.cdc.gov/rsv/hcp/clinical-overview/index.html. Last accessed: October 2024
[7] A.Njue et al., "Systematic Literature Review of Risk Factors for Poor Outcomes Among Adults With Respiratory Syncytial Virus Infection in High-Income Countries" in *Open Forum Infectious Diseases*, Volume 10, Issue 11, November 2023, ofad513, https://doi.org/10.1093/ofid/ofad513