Press release

For media and investors only

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GSK's AREXVY associated with reductions in certain RSV-related risks including heart attack, stroke and severe flare-ups of COPD and asthma, real world study shows

- Reduction observed in RSV-related hospitalizations in adults aged ≥60 years[1]
- An observed reduction in major adverse cardiovascular events* in adults aged ≥60 years[‡2] during RSV-related hospitalization
- Risk reduction observed against severe flare-ups of chronic obstructive pulmonary disease (COPD) and asthma[†2] during RSV-related hospitalization

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GSK plc (LSE/NYSE: GSK) today announced new effectiveness data for AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) at RSVVW'26, the 9th Conference of the Respiratory Syncytial Virus Foundation (ReSViNET) in Rome, Italy. GSK is presenting 19 abstracts at the congress and supporting a further 3, reflecting GSK's leadership in research and prevention of RSV. AREXVY is indicated for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older, as well as individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

Hospitalization places a significant burden on patients and health systems, particularly in winter months.[3,4] A retrospective cohort study was undertaken in the US with the primary objective to assess the effectiveness of GSK's RSV vaccine in helping to prevent RSV-related hospitalization in adults aged ≥60 years. It included over 2.5 million people, of which 520,440 were vaccinated individuals who were exact matched 1:4 to 2,081,760 unvaccinated individuals.[1,2] The vaccinated group received vaccination between August 1, 2023, and May 31, 2024, and the study observed risk reductions in this season.

For GSK's RSV vaccine, the study showed an association with 75.6% vaccine effectiveness (VE) against RSV-related hospitalization at a median follow-up of 5.6 months (maximum 9.7 months) post-vaccination (unvaccinated group, n=1,419/2,081,760; vaccinated group, n=95/520,440; 95% confidence interval: 69.8–80.2%).[1,5]

Further exploratory endpoints showed an association with 63.1% VE against major adverse cardiovascular events (MACE), including heart attack and stroke, during RSV-related hospitalization among adults aged ≥60 years,[‡2,5] (unvaccinated group, n=212/699,177; vaccinated group, n=21/170,803; 95% confidence interval: 41.8–76.6%). They also showed an association with 74.4% and 61.6% VE against severe COPD and asthma flare-ups, respectively, during RSV-related hospitalization among adults aged ≥60 years[†2,5] (COPD unvaccinated group, n=265/286,406; vaccinated group, n=20/76,209; 95% confidence interval: 59.3–83.9%. Asthma unvaccinated group, n=57/190,590; vaccinated group, n=7/53,636; 95% confidence interval: 9.1–83.7%).

In a separate nationwide cohort study conducted in Denmark in COPD patients aged ≥60 years,[≠] it was observed that GSK's RSV vaccine was associated with VE of 100% in preventing RSV-related hospitalizations (unvaccinated group, n=115/89,376; vaccinated group, n=0/7448; 95% confidence interval: 71.1–100%).[6]

Analyses from both the US and Denmark studies will be presented at RSVVW'26.

While observational research cannot demonstrate a causal association between RSV vaccination and reduced RSV-related risks, these findings add to a growing body of evidence of observed risk reductions in cardiovascular and

respiratory underlying diseases. GSK's RSV vaccine is indicated for the prevention of RSV-lower respiratory tract disease (LRTD).

Deepak L. Bhatt, MD, MPH, MBA, Director of Mount Sinai Fuster Heart Hospital and the Dr. Valentin Fuster Professor of Cardiovascular Medicine at the Icahn School of Medicine at Mount Sinai in New York, said: "In the real-world data being presented at RSVVW'26, it is observed that RSV vaccination could help reduce the risk of certain serious RSV-related outcomes, potentially including major adverse cardiovascular events such as heart attack and stroke, as well as severe flare-ups of COPD and asthma. These new data are a significant step in our understanding of how to help prevent such RSV-related health outcomes. I look forward to more data investigating this association further."

Christian Felter, GSK Global Medical Lead, RSV, said: "These data underscore the value of our RSV vaccine in its observed association with helping to prevent RSV-related hospitalization and reducing the risk of acute events of certain chronic conditions associated with this potentially serious disease. We are proud of our contribution at the forefront of generating innovative research in RSV to inform the clinical community and improve outcomes for patients."

Notes:

* Major adverse cardiovascular events (MACE) were defined in this analysis as: myocardial infarction, ischemic stroke, heart failure-related hospitalization, or unstable angina-related hospitalization.

‡ among US adults aged 60 years and older with existing cardiovascular disease (CVD)

† among US adults aged 60 years and older with existing chronic obstructive pulmonary disease (COPD) and asthma, respectively

≈ Dr. Bhatt is a paid consultant to GSK, who sponsored this study, and a co-author of a related study (#482 below).

≠ among Danish adults aged 60 years and older with existing chronic obstructive pulmonary disease (COPD)

Full list of GSK's presentations at RSVVW'26

Abstract name	Presenter	Presentation details
RSV-related health outcomes and real-world evidence in older adults (≥60 years)		
Adjuvanted RSVPreF3 vaccine effectiveness against RSV-related hospitalisation among US adults aged 60 years and older	Elizabeth La	#429
Effectiveness of adjuvanted RSVPreF3 vaccine in preventing major adverse cardiovascular events, severe asthma exacerbations, and severe chronic obstructive pulmonary disease (COPD) exacerbations among US adults aged 60 years and older	Elizabeth La	#428
Real-world evidence of the adjuvanted RSVPreF3 vaccine's uptake and effectiveness among Chronic Obstructive Pulmonary Disease patients in Denmark: A nationwide cohort study	Maria João Fonseca	#244
Public Health Impact of Adjuvanted RSVPreF3 Vaccination in Adults Aged 60+ Years in four major metropolitan areas of China: Beijing, Chengdu, Guangzhou and Shanghai	Eleftherios Zarkadoulas	#439
Beyond the acute episode: persistent functional and emotional burden after RSV hospitalisation in adults ≥65 years	Alejandro Orrico-Sánchez	#403
Protecting adults aged ≥18 years AIR for severe RSV disease		

Risk of major adverse cardiovascular events after severe respiratory syncytial virus (RSV) disease among adults in the United States	Elizabeth La	#482
Adjuvanted RSVPreF3 is non-inferior in adults 18–49 years of age (YOA) at increased risk for RSV disease compared to older adults ≥60 YOA: a post-hoc analysis by baseline medical condition	Veronica Hulstrøm	#310
Cost-Effectiveness of the Adjuvanted RSV Prefusion F Vaccine in Adults 50–59 at Increased Risk in Italy	Eleftherios Zarkadoulas	#381
Burden of RSV infection among hospitalised adults aged ≥50 years with acute respiratory infection in Türkiye: a prospective, multicentre study	Adriana Guzman-Holst	#374
Valuating RSV-related health states for younger adults and their caregivers in the United States – a time trade-off and sleep trade-off study	Maria João Fonseca	#235
Productivity and time loss estimates for adults with respiratory syncytial virus (RSV) disease and their caregivers in the United States (US) and Germany: a targeted literature review	Maria Waize	#284
Serious adverse events and potential immune-mediated diseases following one dose of adjuvanted RSVPreF3 in adults aged ≥18 years: pooled safety analysis from five clinical trials	Veronica Hulstrøm	#461
Societal impact of RSV vaccination		
The Hospital Burden of Disease, Mortality and Cost of Respiratory Syncytial Virus (RSV) in Queensland, Australia, 2024–2025	Krispin Hajkowicz	#356
Humanistic burden of respiratory syncytial virus disease in immunocompromised and high-risk adults in Germany and the United States: A cross-sectional concept elicitation study	Adriana Guzman-Holst	#291
Modeled impact of racial and ethnic disparities in RSV vaccination uptake on RSV disease burden averted among US adults aged ≥60 years.	Elizabeth La	#418
Respiratory Syncytial Virus Hospitalizations Among Adults in Thailand: A Nationwide Retrospective Observational Study (RSV-HAT)	Chadakan Yan	#308
RSV-related knowledge and practices among US adults at increased risk of severe RSV disease	Elizabeth La	#415
Unlocking the value of RSV adult vaccination with adjuvanted RSVPreF3 Vaccine in Italy: A return on investment analysis using an integrated actuarial-macroeconomic model	Eleftherios Zarkadoulas	#243
Reducing the Burden on the Healthcare System Through the Introduction of RSV Vaccination in Germany	Maria Waize	#365
From value to equity: a distributional return of investment approach of RSV vaccination with RSVPreF3 OA in Spain with an actuarial and macroeconomic model	Eleftherios Zarkadoulas	#481
Others		
High-content spectral flow cytometric profiling of RSV-PreF3 and RSV-PostF–specific B cells after $AS01_E$-adjuvanted or unadjuvanted RSVPreF3 vaccination	Stephane Guillaume	#286
Establishing a Controlled Human Infection Model with a contemporary Respiratory Syncytial Virus B challenge agent in healthy volunteers	Ingrid M.C. de Visser – Kamerling	#283

About the US real-world evidence study

The two abstracts presented report findings from a retrospective cohort study conducted using US administrative claims data from the Optum Research Database (ORD; August 2022–May 2024).[1,2] The first abstract evaluates VE against RSV-related hospitalization (defined by International Classification of Diseases, Tenth Revision, Clinical Modification diagnosis codes for RSV).[2] The second abstract estimates VE of GSK's RSV vaccine against MACE, and against severe flare-ups of COPD and asthma.[1] A total of 520,440 vaccinated and 2,081,760 unvaccinated individuals were included in the overall study.[1,2] The analyses included adults aged ≥60 years identified between August 2023–May 2024.[1,2]

About AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted)

AREXVY contains recombinant RSV glycoprotein F stabilized 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-lower respiratory tract disease (LRTD) in individuals 60 years of age and older in more than 65 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 55 countries, including the US and Japan. In the European Economic Area, it is approved for use in adults aged 18 years and older. Please refer to the Product Information (PI) for important dosage, administration, and safety information in Europe at this link: http://www.ema.europa.eu/medicines/human//EPAR/arexvy and in the US at this link: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Arexvy/pdf/AREXVY.PDF

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.

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 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.[7] Adults can be at increased risk for severe RSV disease due to certain comorbidities including COPD, asthma, and chronic heart failure, immunocompromised status, or advanced age.[8] In the US, it is estimated that there are between 6,000 and 10,000 RSV-related deaths annually in older adults and between 110,000 and 180,000 hospitalizations in people aged 50 and over.[9,10] RSV can exacerbate certain medical conditions, and lead to severe illness resulting in hospitalization and even death.[8,11,12] 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.[13,14,15,16]

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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