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Issued: June 26th, 2024, Philadelphia, PA

Statement: US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices updates recommendations on adult RSV vaccines ahead of the next season

- ACIP recommends routine RSV immunization for all adults aged 75 and older
- ACIP recommends RSV immunization for adults aged 60-74 who are at increased risk for severe RSV disease
- ACIP postpones vote on recommending RSV immunization for adults aged 50-59 at increased risk for severe RSV disease until additional data are available

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GSK plc (LSE/NYSE: GSK) today announced that the US Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted in favor of recommending the routine use of RSV vaccines in all adults aged 75 and above. They also recommended RSV immunization for adults aged 60-74 who are at increased risk for severe RSV disease. These recommendations replace the previous recommendation for shared clinical decision-making in these age groups and have the potential to positively impact access to RSV immunization particularly for the estimated 27 million US adults aged 75 and older[1].

ACIP postponed a vote on a recommendation for adults aged 50-59 at increased risk for RSV-LRTD until additional data become available. GSK continues to generate data, building on the existing robust clinical data package, to help inform future policy decision making. AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) is the first and only vaccine FDA-approved for adults aged 50-59 who are at increased risk for RSV-LRTD, approved June 7th, 2024.

Over 13 million US adults aged 50-59 have at least one known medical condition that increases their risk for severe RSV outcomes.[2] Each year, RSV is estimated to cause approximately 42,000 hospitalizations in adults aged 50-64 years[3] .

In making its recommendations, the ACIP evaluated available efficacy and immunogenicity data on each licensed RSV vaccine for adults, including AREXVY, and considered the latest real-world surveillance data from the FDA and CDC databases including post marketing safety data on Guillain Barre syndrome (GBS). In GSK's view, the totality of evidence provides further confidence in the unchanged and favorable benefit-risk profile of AREXVY.

The ACIP recommendations will be forwarded to the director of the CDC and the US Department of Health and Human Services for review and approval. Once approved, the final recommendations will be published in a future Morbidity and Mortality Weekly Report (MMWR).

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.

In May 2023, the FDA approved GSK's RSV vaccine for the prevention of RSV-LRTD in individuals 60 years of age and older. In June 2024, the FDA also approved the vaccine for individuals 50-59 who are at increased risk for RSV-LRTD. 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.

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The vaccine has also been approved for the prevention of RSV-LRTD in individuals 60 years of age and older in over 40 countries. Regulatory reviews for both the use of the vaccine in individuals 60 years of age and older and those aged 50-59 at increased risk are ongoing in multiple countries. 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.

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
- 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.

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. RSV can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalization, and death.[4] Each year, RSV is estimated to cause approximately 177,000 hospitalizations in adults 65 years and older[5] and 42,000 in adults aged 50-64 years old in the US[3].

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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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 the company's Annual Report on Form 20-F for 2022, and Q1 Results for 2024.

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References

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[1] United States Census Bureau. International Database: World Population Estimates and Projections: USA, 2024.
[2] Horn et al, "Disparities in Risk Factors for Severe Respiratory Syncytial Virus Disease among Adults in the United States", Abstract presented at National Foundation for Infectious Diseases – 27th Annual Conference on Vaccinology Research – NFID 2024; May 8-10, 2024.
[3] 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] Falsey, AR *et al*. "Respiratory syncytial virus infection in elderly and high-risk adults", in *New Engl J Med* 2005; 352:1749-59.