Stock-exchange announcement
For media and investors only

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AREXVY recommended for adults aged 50-59 at increased risk for severe respiratory syncytial virus (RSV) disease by US Advisory Committee on Immunization Practices

- Over 13 million adults aged 50-59 at increased risk in the US can potentially benefit from RSV immunization[1]
- RSV causes an estimated 42,000 hospitalizations* each year in adults aged 50-64 years old in the US[2]

GSK plc (LSE/NYSE: GSK) is pleased that the Advisory Committee on Immunization Practices (ACIP) voted in favor of recommending the use of RSV vaccines including GSK's AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) in adults aged 50-59 who are at increased risk for severe RSV disease. This includes people with conditions like COPD, asthma, diabetes, heart disease and those in residential care[3]. This expands on ACIP's previous vote in June 2024 to recommend RSV vaccines for adults aged 60-74 who are at increased risk and all adults aged 75 and older. 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.

A systematic review of studies in the US shows that RSV is estimated to cause 42,000 hospitalizations* each year in adults aged 50-64 years old.[2] Adults with underlying medical conditions, such as chronic obstructive pulmonary disease (COPD), asthma, heart failure and diabetes are at increased risk from severe consequences from an RSV infection compared to those without these conditions.[4,5] RSV can exacerbate these conditions and lead to pneumonia, hospitalization, or death.[5]

Tony Wood, Chief Scientific Officer, GSK: "We are pleased with ACIP's recommendation to expand the benefits of RSV immunization to more than 13 million adults aged 50-59 who are at increased risk for the severe consequences of this virus. RSV can have a significant impact for those with underlying medical conditions. We look forward to helping protect more people with RSV vaccination."

In making its recommendation, the ACIP considered positive results from a phase III trial [NCT05590403][6] evaluating the immune response and safety of GSK's RSV vaccine in adults aged 50-59, including those at increased risk for RSV-LRTD due to certain underlying medical conditions compared to older adults aged 60 years and older where efficacy has been demonstrated after a single dose of GSK's RSV vaccine.

The ACIP recommendations will be forwarded for review and approval. Once approved, the final recommendations will be published to advise healthcare providers on appropriate use of the vaccine and to inform insurance coverage.

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.

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* adjusted for under-detection

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The vaccine has been approved for the prevention of RSV-LRTD in individuals 60 years of age and older in 61 countries, including Europe, Japan and US. In addition, it is approved in the US, EU/EEA countries and Japan for use in individuals aged 50-59 who are at increased risk for lower respiratory disease caused by RSV due to certain underlying medical conditions. Regulatory reviews for this extended indication are ongoing in other countries.

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 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
- 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. Adults can be at increased risk for RSV disease due to 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] Each year, RSV is estimated to cause approximately 177,000 hospitalizations in adults 65 years and older[7] and 42,000* in adults aged 50-64 years old in the US.[2]

*adjusted for under-detection

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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024.

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