Stock-exchange announcement

For media and investors only

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US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices votes to recommend AREXVY for the prevention of RSV disease in adults aged 60 and older with shared clinical decision making

- Launch is planned in the US before the 2023 RSV season
- Committee recommendations mean over 55 million older adults in the US could have access to RSV vaccination for the first time[1]
- RSV causes approximately 177,000 hospitalizations and 14,000 deaths in adults aged 65 years and older in the US each year[2,3,4]

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 use of AREXVY (respiratory syncytial virus vaccine, adjuvanted) in adults aged 60 and older using shared clinical decision making. Shared clinical decision making empowers patients in consultation with their healthcare providers to determine whether RSV vaccination is appropriate for them.

There are an estimated 55.8 million people aged 65 and older in the US[1] who are at increased risk of RSV, a common, contagious virus that can lead to serious respiratory illness.[2] RSV causes approximately 177,000 hospitalizations and an estimated 14,000 deaths in this age group in the US each year.[2,3,4] For adults 60 and older, data suggest an increased risk for severe RSV infection that can lead to hospitalization.[5,6] Older adults, including those with underlying medical conditions*, such as chronic heart disease, chronic lung disease or diabetes, are at high risk of severe RSV illness and account for the majority of RSV hospitalizations.[5]

Tony Wood, Chief Scientific Officer, GSK, said: "GSK's successful development of an RSV vaccine to help protect older adults from RSV lower respiratory tract disease (LRTD) represents a major scientific advance, resulting from years of collaboration across academia, industry, and research centers. We are grateful to the ACIP and CDC for recognizing the potential of AREXVY and look forward to partnering with public health officials, healthcare professionals and payers to make it available for eligible older adults in the US before this year's RSV season begins."

In making its recommendation, the ACIP considered evidence from the comprehensive data package supporting the vaccine, including in older adults with underlying medical conditions. This includes results from the first season of the pivotal AReSVi-006 (Adult Respiratory Syncytial Virus) phase III trial, published in the *New England Journal of Medicine* in February 2023.[7] During the ACIP meeting, GSK also presented data from the Northern Hemisphere second season of the trial, which remains ongoing to explore the effect of the vaccine over multiple seasons and the optimal timing for potential revaccination. These data will be submitted to the US Food and Drug Administration (FDA) for review.

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) to advise healthcare providers on appropriate use of the vaccine.

* According to the CDC, adults aged 60 and older at even greater risk of severe respiratory illness include those with chronic lung diseases, chronic cardiovascular diseases, immune-compromise, hematologic disorders, neurologic disorders, endocrine disorders, kidney and liver disorders and other factors [8]

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About AREXVY (respiratory syncytial virus vaccine, adjuvanted)
Respiratory syncytial virus vaccine, adjuvanted, contains recombinant glycoprotein F stabilized in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary $AS01_E$ adjuvant.[7]

The vaccine was approved by the US FDA on May 3, 2023, for the prevention of LRTD caused by RSV in individuals 60 years of age and older.[9]

In clinical trials, the vaccine was generally well tolerated. The most frequently observed solicited adverse events were injection site pain, fatigue, myalgia, headache, and arthralgia. These were generally mild to moderate and transient.[7]

In June 2023, the European Commission authorized the vaccine for active immunization for the prevention of LRTD caused by RSV in adults aged 60 years and older.[10] Regulatory reviews in Japan and other counties are ongoing.

The vaccine is not approved anywhere else in the world. The proposed trade name remains subject to regulatory approval in other markets.

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

Please see the full US Prescribing Information: https://www.fda.gov/media/167805/download

Important Safety Information for AREXVY

The following is based on the US Prescribing Information for AREXVY. Please consult the full Prescribing Information for all the labelled safety information.

- Do not administer AREXVY to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of AREXVY.
- Appropriate medical treatment and supervision must be available to manage possible 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.
- The most commonly reported (≥10%) adverse reactions were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%).
- Vaccination with AREXVY may not result in protection of all vaccine recipients.

About RSV in older adults
RSV is a common contagious virus affecting the lungs and breathing passages.[3] Older adults are at high risk for severe disease due in part to age-related decline in immunity[3], and older adults with underlying conditions are at even greater risk for severe disease.[5] RSV can exacerbate conditions, including chronic obstructive pulmonary disease (COPD), asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalization, and death.[2] Each year, approximately 177,000 adults 65 years and older are hospitalized in the US due to RSV; an estimated 14,000 cases result in death.[2,3,4] For adults 60 and older, data suggest an increased risk for severe RSV infection that can lead to hospitalization.[5,6] Adults with underlying conditions are more likely to seek medical services and have higher hospitalization rates than adults without these conditions.[5]

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, GSK's Q1 Results for 2023 and any impacts of the COVID-19 pandemic.

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References

1. United States Census Bureau. The older population: 2020. Accessed May 2023. Available at: https://www2.census.gov/library/publications/decennial/2020/census-briefs/c2020br-07.pdf
2. Centers for Disease Control and Prevention. RSV in Older Adults and Adults with Chronic Medical Conditions. Accessed May 2023. Available at: www.cdc.gov/rsv/high-risk/older-adults.html
3. National Foundation for Infectious Diseases. Respiratory Syncytial Virus. Accessed May 2023. Available at: www.nfid.org/infectious-disease/rsv/
4. Falsey AR, et al. Respiratory syncytial virus infection in elderly and high-risk adults. N Engl J Med 2005; 352:1749-1759.
5. Tseng HF, et al. Severe morbidity and short- and mid- to long-term mortality in older adults hospitalized with respiratory syncytial virus infection. J Infect Dis. 2020;222(8):1298-1310. doi:10.1093/infdis/jiaa361.
6. Belongia EA, et al. Clinical features, severity, and incidence of RSV illness during 12 consecutive seasons in a community cohort of adults ≥60 years old. Open Forum Infect Dis. 2018;5(12):ofy316. doi:10.1093/ofid/ofy316.
7. Papi et al. Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults. N Engl J Med 2023; 388:595-608.
8. CDC presentation. 21 June 2023. Available at: www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-06-21-23/07-RSV-Adults-Britton-508.pdf
9. US FDA new release. Issued 3 May 2023. Available at: www.fda.gov/news-events/press-announcements/fda-approves-first-respiratory-syncytial-virus-rsv-vaccine
10. European Medicines Agency. Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E. Available at: www.ema.europa.eu/en/medicines/human/EPAR/arexvy#authorisation-details-section