US press release

For media and investors only

Issued: 17 August 2023, Philadelphia, PA

GSK announces AREXVY, its respiratory syncytial virus (RSV) vaccine, is now available at all major US retail pharmacies

- Ahead of the fall and winter RSV season, AREXVY is now widely available in major retail pharmacies and anticipated to be covered by most Medicare and commercial insurance plans

GSK plc (LSE/NYSE: GSK) today announced that AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) is now available in the US at all major retail pharmacies. In June, the Advisory Committee on Immunization Practices (ACIP) recommended that persons 60 years of age and older may receive a single dose of RSV vaccine, using shared clinical decision making. Shared clinical decision making empowers patients, in consultation with their healthcare providers, to decide whether RSV vaccination is appropriate for them. AREXVY is indicated for the prevention of RSV-lower respiratory tract disease (LRTD) in individuals aged 60 years and older.

Under the Inflation Reduction Act, patients with Medicare Part D will pay no out-of-pocket expenses. As part of the Affordable Care Act, AREXVY may be covered for commercially insured patients at no cost when administered in-network. Patients should ask their doctor or pharmacist if AREXVY is covered.

Rob Truckenmiller, Senior Vice President, Head of US Vaccines, GSK, said: "We are excited to announce that AREXVY is now available to older adults in major retail pharmacies across the US ahead of this year's RSV season. As the makers of the first FDA-approved RSV vaccine for older adults, we're hopeful that RSV vaccines, like AREXVY, will help reduce the considerable clinical, economic, and human impact that RSV has on older adults and our public health system."

There are an estimated 76.5 million people aged 60 and older in the US.[1] Older adults, including those with underlying medical conditions, such as chronic heart disease, chronic lung disease or diabetes, are at increased risk for RSV-associated hospitalization.[2] RSV causes approximately 177,000 hospitalizations and an estimated 14,000 deaths in adults aged 65 and older in the US each year.[3] For adults 60 and older, data suggest an increased risk for severe RSV infection that can lead to hospitalization.[4,5]

About AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted)

AREXVY, contains recombinant respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary AS01$_E$ adjuvant.[6]

AREXVY was approved by the US Food and Drug Administration (FDA) on May 3rd, 2023, for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults aged 60 and older. It was the world's first vaccine for RSV for older adults, a common, contagious virus that can lead to serious respiratory illness.[7]

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.[6]

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

US press release

For media and investors only

Please see the full US Prescribing Information.

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.

- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, 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 adverse reactions (≥10%) 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.[8] Older adults are at high risk for severe disease due in part to age-related decline in immunity[8], and older adults with underlying conditions are also at high risk for severe disease.[4] 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.[9] 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.[3] For adults 60 and older, data suggest an increased risk for severe RSV infection that can lead to hospitalization.[4,5] Adults with underlying conditions are more likely to seek medical services and have higher hospitalization rates than adults without these conditions.[4]

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.

GSK enquiries

Media	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

US press release
For media and investors only

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

References

1. United States Department of Health and Human Services. Administration for Community Living. 2021 Profile of Older Americans. November 2022. Accessed August 2023. Available at: https://acl.gov/sites/default/files/Profile%20of%20OA/2021%20Profile%20of%20OA/2021ProfileOlderAmericans_508.pdf
2. Melgar M, Britton A, Roper LE, et al. Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:793–801. DOI: http://dx.doi.org/10.15585/mmwr.mm7229a4.
3. Falsey AR, et al. Respiratory syncytial virus infection in elderly and high-risk adults. N Engl J Med 2005; 352:1749-1759.
4. 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.
5. 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.
6. Papi et al. Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults. N Engl J Med 2023; 388:595-608.
7. US FDA news release. Issued 3 May 2023. Available at: www.fda.gov/news-events/press-announcements/fda-approves-first-respiratory-syncytial-virus-rsv-vaccine
8. National Foundation for Infectious Diseases. Respiratory Syncytial Virus. Accessed August 2023. Available at: www.nfid.org/infectious-disease/rsv/
9. Centers for Disease Control and Prevention. RSV in Older Adults and Adults with Chronic Medical Conditions. Accessed August 2023. Available at: www.cdc.gov/rsv/high-risk/older-adults.html