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GSK's RSV vaccine, AREXVY, accepted under Priority Review in US for the prevention of RSV disease in adults aged 50-59 at increased risk

- Application supported by positive results of a phase III trial showing immune response and acceptable tolerability profile in this population
- Adults aged 50 and above with underlying medical conditions are at increased risk for RSV disease^{1,2,3}
- GSK is the first company to file for regulatory approval to extend RSV vaccination to adults aged 50-59 at increased risk
- US FDA has set a Prescription Drug User Fee Act action date of June 7, 2024

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has accepted under Priority Review an application to extend the indication of GSK's adjuvanted respiratory syncytial virus (RSV) vaccine to adults aged 50-59 who are at increased risk for RSV disease. If approved, GSK's RSV vaccine would be the first vaccine available to help protect this population. AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) is currently approved in the US in adults aged 60 and over for the prevention of lower respiratory tract disease (LRTD) caused by RSV.

The application is supported by positive results from a phase III trial [NCT05590403]⁴ 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 underlying medical conditions. GSK used a Priority Review Voucher to reduce the US FDA review period of a supplemental Biologics License Application (sBLA) by four months. The Prescription Drug User Fee Act date, the FDA action date for their regulatory decision, is June 7, 2024.

The burden of RSV disease in adults is likely to be underestimated due to lack of awareness, a lack of standardized testing, and under-detection in surveillance studies.⁵ People with underlying medical conditions, such as chronic obstructive pulmonary disease (COPD), asthma, chronic heart failure⁶ and diabetes,⁷ are at increased risk for RSV disease. RSV can exacerbate these conditions and lead to pneumonia, hospitalization, or death.⁸

About GSK's RSV Vaccine

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.

The FDA has approved GSK's RSV vaccine for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. 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 also been approved for the prevention of RSV-LRTD in individuals 60 years of age and older in Europe, Japan, UK, Canada and several other countries. Regulatory reviews in multiple countries are ongoing. The proposed trade name remains subject to regulatory approval in other markets.

Press release

For media and investors only



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 indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in individuals 60 years of age and older.

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 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 ($\geq 10\%$) 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

Please see full [Prescribing Information](#).

About the NCT05590403 Trial

NCT05590403 is a phase III, placebo-controlled, observer-blind, randomized, multi-country immunogenicity trial to evaluate the non-inferiority of the immune response and evaluate safety in participants aged 50 to 59 at increased risk of RSV-LRTD compared to older adults aged 60 years and above after a single dose of GSK's RSV vaccine.

The study assessed the immune response in participants aged 50 to 59 with pre-defined stable chronic diseases leading to an increased risk of RSV disease (n=570). Immune responses in a broader group of participants aged 50-59 years without these pre-defined chronic diseases (n=570) were also evaluated compared to adults aged 60 and older. The trial's primary endpoints were RSV-A and RSV-B neutralization titers of both groups of 50 to 59 year olds at one month after the vaccine administration compared to adults aged 60 and older. There were also safety and immunogenicity secondary and tertiary endpoints.

Results from this trial will be presented at upcoming medical conferences and submitted for peer-reviewed publication. The data are being submitted to other regulators to support potential label expansions.

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.⁸ RSV can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalization, and death.⁸ 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.⁶

Please see the full US Prescribing Information:

https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Arexvy/pdf/AREXVY.PDF

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 Q4 Results for 2023.

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References

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³ Begley KM *et al.* Prevalence and Clinical Outcomes of Respiratory Syncytial Virus vs Influenza in Adults Hospitalized With Acute Respiratory Illness From a Prospective Multicenter Study. *Clin Infect Dis.* 2023 Jun 8;76(11):1980-1988. doi: 10.1093/cid/ciad031.

⁴ ClinicalTrials.gov, A Study on the Immune Response and Safety of a Vaccine Against Respiratory Syncytial Virus Given to Adults 50-59 Years of Age, Including Adults at Increased Risk of Respiratory Syncytial Virus Lower Respiratory Tract Disease, Compared to Older Adults 60 Years of Age and Above 2023. NCT05590403. <https://www.clinicaltrials.gov/study/NCT05590403>.

⁵ Savic M, Penders Y, Shi T, Branche A, Pirçon J-Y. Respiratory syncytial virus disease burden in adults aged 60 years and older in high-income countries: a systematic literature review and meta-analysis, *Influenza Other Respir Viruses* 2022 2023; 17:e13031.

⁶ Falsey, AR *et al.* Respiratory syncytial virus infection in elderly and high-risk adults, in *New Engl J Med* 2005; 352:1749-59.

⁷ Richard Osei-Yeboah *et al.*, Respiratory syncytial virus-associated hospitalisation in adults with comorbidities in two European countries, PROMISE investigators, preprint, August 2023.

⁸ Centers for Disease Control and Prevention (CDC), RSV in Older Adults and Adults with Chronic Medical Conditions, 2023.