GSK

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GSK shares positive data for AREXVY, its respiratory syncytial virus (RSV) older adult vaccine, indicating protection over two RSV seasons

- New results from the ongoing AReSVi-006 phase III trial show vaccine efficacy against RSV-lower respiratory tract disease and severe disease over two full RSV seasons, including in participants with underlying medical conditions
- Safety and reactogenicity data were consistent with initial results from the phase III program
- The clinical development program will continue to evaluate longer term follow up and the optimal timing for revaccination

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GSK plc (LSE/NYSE: GSK) today announced new data from the AReSVi-006 (**A**dult **R**espiratory **S**yncytial **V**irus) phase III trial evaluating the efficacy of a single dose of AREXVY (respiratory syncytial virus vaccine, adjuvanted) against lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults aged 60 years and older over multiple RSV seasons and after annual revaccination.

Efficacy of a single dose over two seasons
The results show that one dose of the vaccine is efficacious against RSV-LRTD and severe LRTD over two full RSV seasons.

	Vaccine efficacy		
Endpoint	**Season one efficacy** Primary endpoint: 6.7 months median follow up	**Mid-season two efficacy*** Descriptive secondary endpoint: 14 months median follow up	**Cumulative efficacy over two seasons*** Confirmatory secondary endpoint: 18 months median follow up
RSV-LRTD	**82.6%** 96.95% CI, 57.9–94.1 7 of 12,466 vs 40 of 12,494	**77.3%** 95% CI, 60.2-87.9 15 of 12,469 vs 85 of 12,498	**67.2%** 97.5% CI, 48.2–80.0 30 of 12,469 vs 139 of 12,498
Severe LRTD	**94.1%** 95% CI, 62.4–99.9 1 of 12,466 vs 17 of 12,494	**84.6%** 95% CI, 56.4-96.1 4 of 12,469 vs 33 of 12,498	**78.8%** 95% CI, 52.6–92.0 7 of 12,469 vs 48 of 12,498

*The vaccine efficacy is estimated using a Poisson model adjusted by age, region and season.

A similar pattern of vaccine efficacy over two seasons was also observed in adults with underlying comorbidities and in advancing age, reinforcing the impact the vaccine could have on those most at risk of the severe outcomes of RSV.

Revaccination
The trial also evaluated efficacy following an annual revaccination schedule as a confirmatory secondary endpoint. Cumulative efficacy over two seasons in participants who received a second dose of the vaccine was 67.1% (97.5% CI, 48.1-80.0, 30 of 12,469 vs 139 of 12,498), suggesting revaccination after 12 months does not appear to confer additional benefit for the overall population. The clinical development program will continue to evaluate longer term follow up and the optimal timing for potential revaccination.

Tony Wood, Chief Scientific Officer, GSK, said: “Our goal is to provide a high level of protection for older adults most at risk from RSV. These data show the efficacy of a single dose of our vaccine over two RSV seasons against RSV-LRTD, including in the populations most at risk due to age or underlying medical conditions. This reinforces our confidence in its potential to make a significant public health impact. We look forward to discussing these results with regulators and vaccine recommending bodies and to collecting more data from the ongoing clinical development program.”

Safety and reactogenicity data were consistent with initial observations from the phase III program. The vaccine was generally well tolerated. The most frequently observed adverse events were injection site pain, fatigue, myalgia, headache, and arthralgia. These were generally mild to moderate and transient.

GSK will present these data at the US Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) meeting on June 21, 2023. Data from two influenza co-administration trials (quadrivalent high dose and quadrivalent adjuvanted) will also be presented, adding to the seasonal quadrivalent influenza vaccination co-administration data in the current US product label. These data will be submitted to the US Food and Drug Administration (FDA) and other regulators for review.

About AReSVi-006
This is a randomized, placebo-controlled, observer-blind, multi-country phase III trial to demonstrate the efficacy of a single dose of GSK's adjuvanted RSV older adult vaccine over three years and following an annual revaccination schedule in adults aged 60 years and above. Approximately 25,000 participants were enrolled from 17 countries. The trial’s primary endpoint was vaccine efficacy against RSV-LRTD after one RSV season. Initial results were published in the *New England Journal of Medicine* in February 2023.

After the first season, 12,469 participants in the vaccine arm were re-randomized to receive either the RSV vaccine or placebo and were followed up for occurrence of RSV-LRTD. Vaccine efficacy of a single dose against RSV-LRTD after two seasons and vaccine efficacy after annual revaccination were confirmatory secondary endpoints.

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.

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.

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

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. Older adults are at high risk for severe disease due in part to age-related decline in immunity, and older adults with underlying conditions are at even greater risk for severe disease. 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. 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.[1] For adults 60 and older, data suggest an increased risk for severe RSV infection that can lead to hospitalization.[2,3] Adults with underlying conditions are more likely to seek medical services and have higher hospitalization rates than adults without these conditions.

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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