Stock-exchange announcement

For media and investors only

Issued: 8 October 2024, London UK

GSK presents positive data for *Arexvy*, its respiratory syncytial virus (RSV) vaccine, indicating protection over three RSV seasons

- GSK's RSV vaccine is the only RSV vaccine with efficacy and safety data available through 3 full seasons, including in people at increased risk
- Safety and reactogenicity data are consistent with previous results from phase III programme
- GSK will continue to provide data on longer term follow-up to help recommending bodies determine future revaccination schedules

---

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, recombinant adjuvanted) against lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults aged 60 years and older, including those at increased risk over three full RSV seasons (NCT04886596).[1] These data will be presented today at the CHEST 2024 Annual Meeting, organised by the American College of Chest Physicians.

Arexvy is the world's first RSV vaccine and was approved based on exceptional efficacy in adults aged 60 and older, including those who are at increased risk due to certain underlying medical conditions. Today's results indicate that after a single dose of GSK's RSV vaccine, cumulative efficacy over three full RSV seasons was clinically meaningful at 62.9% against RSV-LRTD (97.5% CI, 46.7-74.8, 48 of 12,468 vs 215 of 12,498) and 67.4% against severe RSV-LRTD (95% CI, 42.4-82.7,15 of 12,468 vs 75 of 12,498) compared to placebo. In the third season, the vaccine's efficacy was 48.0% against RSV-LRTD (95% CI, 8.7-72.0, 16 of 4,988 vs 61 of 10,031).

These results include efficacy against different RSV subtypes, in adults with advancing age (70-79 years of age), and those with certain underlying medical conditions. Since RSV can exacerbate medical conditions and potentially lead to hospitalisations, cumulative efficacy over three RSV seasons has the potential for significant health impact. It has the potential to offer health care professionals flexibility to administer the vaccine year-round. Over time, revaccination is expected to be required to maintain an optimal level of protection. GSK will continue to share efficacy and immune response data, including on revaccination, with recommending bodies to inform decisions on immunisation schedules and future revaccination.

RSV is a common contagious virus affecting the lungs and breathing passages and impacts an estimated 64 million people of all ages globally every year.[2] Adults can be at increased risk for RSV disease due to comorbidities, immune compromised status, or advanced age. RSV can exacerbate multiple conditions, including COPD, asthma, and chronic heart failure, and can lead to severe outcomes, such as pneumonia, hospitalisation, and death.[3] Each year RSV causes over 465,000 hospitalisations and 33,000 deaths in adults aged 60 and older in high-income countries.[4]

Tony Wood, Chief Scientific Officer, GSK, said: "We are excited by these new data which show that a single dose of *Arexvy* could help protect millions of older adults at risk of RSV disease over three seasons to benefit public health. This is the only RSV vaccine with efficacy and safety data available through three full seasons. We will continue to provide data on longer term follow-up to help recommending bodies determine future revaccination schedules."

Stock-exchange announcement

For media and investors only

Endpoint	Season one efficacy*	Season two efficacy	Season three efficacy	Cumulative efficacy over three seasons**
RSV-LRTD	Primary confirmatory endpoint: 6.7 months median follow- up **82.6%** 96.95% CI, 57.9–94.1 7 of 12,466 vs 40 of 12,494	Secondary descriptive endpoint: 6.3 months median follow-up **56.1%** 95% CI, 28.2–74.4 20 of 4,991 vs 91 of 10,031	Secondary descriptive endpoint: 7 months median follow-up **48.0%** 95% CI, 8.7-72.0 16 of 4,988 vs 61 of 10,031	Secondary confirmatory endpoint: 30.6 months median follow-up **62.9% - with season as covariate***** 97.5% CI, 46.7-74.8 48 of 12,468 vs 215 of 12,498 **69.1% - without season as covariate (post-hoc analysis)** 97.5% CI, 55.8-78.9 48 of 12,468 vs 215 of 12,498
Severe LRTD	Secondary descriptive endpoint **94.1%** 95% CI, 62.4–99.9 1 of 12,466 vs 17 of 12,494	Secondary descriptive endpoint **64.2%** 95% CI, 6.19–89.2 5 of 4,991 vs 28 of 10,031	Secondary descriptive endpoint **43.3%** 95% CI, -45.3-81.3 6 of 4,988 vs 21 of 10,031	Secondary descriptive endpoint **67.4% - with season as covariate***** 95% CI, 42.4-82.7 15 of 12,468 vs 75 of 12,498 **72.3 % - without season as covariate (post-hoc analysis)** 95% CI, 51.3 – 85.2 15 of 12,468 vs 75 of 12,498
RSV-LRTD in participants with at least 1 pre-existing comorbidity of interest	Secondary descriptive endpoint **94.6%** 95% CI, 65.9–99.9 1 of 4,937 vs. 18 of 4,861	Secondary descriptive endpoint **51.5%** 95% CI, 7.4 – 76.6 12 of 1,981 vs 48 of 3,895	Secondary descriptive endpoint **57.8 %** 95% CI, 8.0-83.0 8 of 2,000 vs 37 of 3,924	Secondary descriptive endpoint **64.7% - with season as covariate***** 95% CI, 45.1-78.1 25 of 5,014 vs 116 of 4,951 **71.1% - without season as covariate (post-hoc analysis)** 95% CI, 55.2 – 82.0 25 of 5,014 vs 116 of 4,951

* The absolute values are being presented vaccinated group vs placebo group.
** The vaccine efficacy is estimated using a Poisson model adjusted by age, region and season.
*** Seasonality covariate means the data have been adjusted to reflect the variability of disease incidence between different seasons.

Safety and reactogenicity data were consistent with previous results from the phase III programme. In season one, the vaccine was generally well tolerated. The most frequently observed adverse events were injection site pain, fatigue, myalgia, headache, and arthralgia within four days of vaccination.

In addition to the presentation at CHEST, the data will be submitted for scientific peer-reviewed publication and to regulators for review.

*****

Stock-exchange announcement
For media and investors only

About AReSVi-006
This is a randomised, placebo-controlled, double-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 compared to placebo arm. About 25,000 participants have been enrolled from 17 countries. The trial's primary endpoint was vaccine efficacy against RSV-LRTD after one RSV season. Results were published in the *New England Journal of Medicine* in February 2023.[5]

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 and three RSV seasons compared to placebo and vaccine efficacy after annual revaccination compared to placebo were confirmatory secondary endpoints.

About GSK's RSV vaccine
Respiratory Syncytial Virus Vaccine, Adjuvanted, contains recombinant RSV glycoprotein F stabilised in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary AS01$_E$ adjuvant.

In May 2023, GSK's RSV vaccine was first approved by the US FDA for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. Since then, the vaccine has also been approved for the prevention of RSV-LRTD in individuals 60 years of age and older in 50 countries, including Europe and Japan. In addition, it is approved in the US and EU for use in individuals aged 50-59 who are at increased risk due to certain underlying medical conditions. Regulatory reviews for this extended indication are also undergoing review in other countries – including Japan. The proposed trade name remains subject to regulatory approval in other markets.

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 QS-21 STIMULON adjuvant licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc.

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:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Simon Moore	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Annabel Brownrigg Gleeson	+44 (0) 7901 101944	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7736 063933	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

Stock-exchange announcement
For media and investors only

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 GSK's Annual Report on Form 20-F for 2023, and GSK's Q2 Results for 2024.

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

References

[1] Clinicaltrials.gov, "Efficacy Study of GSK's Investigational Respiratory Syncytial Virus (RSV) Vaccine in Adults Aged 60 Years and Above". Available at: https://clinicaltrials.gov/study/NCT04886596 - last accessed: September 2024
[2] National Institute of Allergy and Infectious Diseases, Respiratory Syncytial Virus (RSV). Available at: https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv – last accessed: September 2024
[3] Centers for Disease Control and Prevention (CDC), RSV in Older Adults, 2024. Available at: https://www.cdc.gov/rsv/older-adults/index.html - Last accessed: September 2024
[4] Savic M, et al., "Respiratory syncytial virus disease burden in adults aged 60 years and older in high-income countries: a systematic literature review and meta-analysis", in *Influenza Other Respir Viruses*, 2023, 17(1):e13031, DOI: 10.1111/irv.13031
[5] Papi A. et al, "Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults", in *New England Journal of Medicine*, 2023;388:595-608 DOI: 10.1056/NEJMoa2209604