Stock-exchange announcement

For media and investors only

Issued: 7 June 2023, London UK

European Commission authorises GSK's *Arexvy*, the first respiratory syncytial virus (RSV) vaccine for older adults

- Authorisation will help protect adults 60 years of age and older in 30 European countries* from RSV disease for the first time
- In Europe, RSV leads to over 270,000 hospitalisations and approximately 20,000 in-hospital deaths in adults 60 years of age and older each year
- The authorisation is based on phase III efficacy data in older adults

---

GSK plc (LSE/NYSE: GSK) today announced that the European Commission has authorised *Arexvy* (respiratory syncytial virus vaccine, adjuvanted) for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults 60 years of age and older. This is the first time an RSV vaccine for older adults has been granted European Marketing Authorisation. The first launches are planned ahead of the 2023/2024 RSV season which typically starts in the autumn.

Tony Wood, Chief Scientific Officer, GSK, said: "Thousands of older adults across Europe suffer serious respiratory illness due to RSV each year. This authorisation for *Arexvy* means eligible adults can be vaccinated against RSV disease for the first time, reinforcing GSK's long history of vaccine innovation. Our strong manufacturing capability and scale, including from our vaccine manufacturing site in Belgium, means we are ready to deliver the vaccine as countries begin to launch."

RSV is a common, contagious respiratory virus that leads to over 270,000 hospitalisations and approximately 20,000 in-hospital deaths each year in adults aged 60 years and over in Europe[1]. An estimated 3 million cases of RSV acute respiratory infection (ARI) are reported in this population each year, and the impact on healthcare systems is expected to increase as the population ages[1]. Those with underlying medical conditions, such as diabetes and chronic heart and lung disease, drive the majority of RSV hospitalisations.[2,3]

Dr Alberto Papi, Full Professor of Respiratory Medicine and Head at the University of Ferrara, said: "For most, RSV causes cold-like symptoms. For older adults and those with underlying medical conditions however, it can lead to severe disease and is a leading cause of serious respiratory infections. As scientists, we have been trying to find a solution for over 60 years. I am proud to have been part of the innovation that has resulted in a vaccine now being available to help protect eligible older adults across Europe from severe RSV disease for the first time."

The authorisation is based on GSK's landmark positive pivotal AReSVi-006 (Adult Respiratory Syncytial Virus) phase III trial data. In the trial, the vaccine showed statistically significant and clinically meaningful overall efficacy of 82.6% (96.95% CI, 57.9–94.1, 7 of 12,466 vs 40 of 12,494) against RSV-LRTD in adults aged 60 years and older, meeting the primary endpoint. In addition, efficacy was 94.6% (95% CI, 65.9–99.9, 1 of 4,937 vs 18 of 4,861) in older adults with at least one underlying medical condition of interest, such as certain cardiorespiratory and endocrine-metabolic conditions.

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.

The European Commission's decision follows the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) positive opinion in April 2023. GSK's marketing authorisation application was reviewed under the accelerated assessment mechanism because prevention of RSV disease in the older adult population is considered a major public health interest.

Arexvy was the world's first RSV vaccine to be approved for older adults when, in May 2023, it was approved by the US Food and Drug Administration. Later this month, the Advisory Committee on Immunization Practices (ACIP) will make recommendations on the appropriate use of the vaccine in the US. Regulatory reviews are ongoing in Japan and several other countries.

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

Indication
The European Commission has authorised *Arexvy* for active immunisation for the prevention of LRTD caused by RSV in adults aged 60 years and older. It is also approved in the US. 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 is not approved anywhere else in the world. The proposed trade name remains subject to regulatory approval in other markets.

The *Arexvy* EMA Reference Information, including a full list of adverse events and the complete important safety information in the EU, will shortly be available at this link: www.ema.europa.eu/medicines/human//EPAR/arexvy

A clinical trial investigating RSV vaccination in adults aged 50-59, including participants with underlying comorbidities, is fully recruited. Results are expected in 2023, together with additional results from the AReSVi-006 phase III efficacy trial and the AReSVi-004 immunogenicity trial. These trials continue to evaluate an annual revaccination schedule and protection/immunogenicity over multiple seasons following one dose of the RSV vaccine.

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

About AReSVi-006
This is a randomised, placebo-controlled, observer-blind, multi-country phase III trial to demonstrate the efficacy of a single dose of GSK's adjuvanted RSVPreF3 vaccine in adults aged 60 years and above. Approximately 25,000 participants were enrolled from 17 countries. Initial results were published in the *New England Journal of Medicine* in February 2023.

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. Older adults with underlying medical 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, hospitalisation, and death. In Europe, RSV leads to over 270,000 hospitalisation and approximately 20,000 in-hospital deaths each year in adults aged 60 years and over [1]. Adults with underlying conditions are more likely to seek medical services and have higher hospitalisation 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.

GSK enquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Simon Moore	+44 (0) 20 8047 5502	(London)

Stock-exchange announcement

For media and investors only

	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Nick Stone	+44 (0) 7717 618834	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Josh Williams	+44 (0) 7385 415719	(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)

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.

Registered in England & Wales:
No. 3888792

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

Notes
***** The European Commission has the authority to approve medicines for European Union member states, as well as in the European Economic Area (EEA) countries Iceland, Norway and Liechtenstein.

References

1. 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 November 11. *Available at: https://onlinelibrary.wiley.com/doi/full/10.1111/irv.13031*
2. Centers for Disease Control and Prevention. RSV in Older Adults and Adults with Chronic Medical Conditions. Accessed March 2023. *Available at: www.cdc.gov/rsv/high-risk/older-adults.html*
3. Tseng HF, Sy LS, Ackerson B, 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. *Available at: https://pubmed.ncbi.nlm.nih.gov/32591787/*