Stock-exchange announcement

For media and investors only

Issued: 29 August 2024, London UK

European Commission approves expanded age indication for GSK's *Arexvy,* the first respiratory syncytial virus (RSV) vaccine for adults aged 50-59 at increased risk

- An estimated 20 million adults aged 50-59 in 30 European countries* have a medical condition that increases their risk for RSV disease[1-3]
- Authorisation helps protect this population for the first time ahead of this RSV season
- This follows approval in US, with other countries anticipated, including Japan later this year

---

GSK plc (LSE/NYSE: GSK) today announced that the European Commission has authorised *Arexvy* (respiratory syncytial virus vaccine, recombinant adjuvanted) for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults aged 50-59 who are at increased risk. Since June 2023, GSK's RSV vaccine has been approved in Europe for adults aged 60 and over for the prevention of RSV-LRTD[4].

Adults with underlying medical conditions, such as chronic obstructive pulmonary disease (COPD), asthma, heart failure and diabetes are at increased risk for severe consequences from an RSV infection compared to those without these conditions[5,6]. RSV can exacerbate these conditions and lead to pneumonia, hospitalisation or death.[6]

It is estimated that there are about 65 million adults aged between 50 and 59 in the European Union/European Economic Area[1], with an estimated 20 million of these people (one-third) having at least one underlying medical condition that puts them at increased risk for RSV disease.[2,3]

Tony Wood, Chief Scientific Officer, GSK, said: "Today's approval reflects the importance of broadening the benefits of RSV immunisation to adults aged 50-59 who are at increased risk. RSV infection can have a significant impact on the health of older adults and particularly those with certain existing medical conditions, which can add pressure onto healthcare systems. As we enter the RSV season, we are pleased to be the first to deliver a vaccine to help protect more people in Europe from RSV-LRTD."

The regulatory application was supported by positive results from a phase III trial 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 certain underlying medical conditions.[7]

Prof. Dr. Tino F. Schwarz, Klinikum Würzburg Mitte, Würzburg, Germany said: "There are a great number of patients in the age-group 50-59 years living with certain underlying medical conditions with an increased risk for severe RSV infection. These patients are likely to benefit from the extension of the age indication of the RSV vaccine, helping to reduce the burden of disease of RSV associated LRTDs. I hope that the NITAGs in Europe will rapidly adapt the indication of RSV vaccination to include these patients".

In addition to the US and European approvals, GSK has also filed regulatory submissions to extend the use of this vaccine to adults aged 50-59 at increased risk, including in Japan and other geographies with regulatory decisions undergoing review. Trials evaluating the immunogenicity and safety of the vaccine in adults aged 18-49 at increased risk and immunocompromised adults aged 18 and over are expected to read out later in 2024.

Stock-exchange announcement
For media and investors only

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

In June 2023, the European Commission 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 *Arexvy* EMA Reference Information, including a full list of adverse events and the complete important safety information in the EU, will be available at this link:
www.ema.europa.eu/medicines/human//EPAR/arexvy

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, Japan and US. Regulatory reviews in multiple countries are ongoing. 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.

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 certain underlying medical conditions, immune compromised status, or advanced age.[6] RSV can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death.[6]

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:	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) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

Stock-exchange announcement
For media and investors only

Registered in England & Wales:
No. 3888792

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

Notes:
*estimated from the % of individuals aged 50-59 in France, Italy and Spain with at least one chronic condition[3] extrapolated to the EU/EEA population of 50-59 years in 2024.[1] The European Commission has the authority to approve medicines for the European Union member states, as well as in the European Economic Area (EEA) countries Iceland, Norway and Liechtenstein.

References

1. United Nations. World Population Prospects 2024. Available at: https://population.un.org/wpp/ - accessed in August 2024
2. Zimmerman, RK et al., "Prevalence of high-risk indications for influenza vaccine varies by age, race, and income" in *Vaccine*, 28(39), 6470-6477.3, 2010
3. de Fougerolles, TR. et al, "Public health and economic benefits of seasonal influenza vaccination in risk groups in France, Italy, Spain and the UK: state of play and perspectives" in *BMC Public Health, 24*(1), 1222, 2024
4. *Arexvy | European Medicines Agency (EMA)*. (n.d.). European Medicines Agency (EMA). Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/arexvy - accessed in August 2024
5. Branche AR et al., "Incidence of Respiratory Syncytial Virus Infection Among Hospitalized Adults, 2017–2020" in *Clinical Infectious Diseases*, 74:1004–1011, 2022
6. Centers for Disease Control and Prevention (CDC), RSV in Adults. Available at: https://www.cdc.gov/rsv/older-adults/index.html - accessed in August 2024
7. Ferguson, M. et al., "Noninferior Immunogenicity and Consistent Safety of Respiratory Syncytial Virus Prefusion F Protein Vaccine in Adults 50-59 Years Compared to ≥60 Years of Age" in *Clinical Infectious Diseases*, ciae364, 2024. Advance online publication. doi.org/10.1093/cid/ciae364