Stock-exchange announcement

For media and investors only

Issued: 12 December 2023, London UK

Japan's Ministry of Health, Labour and Welfare accepts *Arexvy* (RSV vaccine) regulatory application to prevent RSV disease in adults aged 50-59 at increased risk

- Submission supported by positive results of a Phase III study showing immune response and safety in adults aged 50-59
- Adults aged 50 and above with certain underlying medical conditions are at increased risk for RSV disease
- GSK is the first company to seek regulatory approval to extend RSV vaccination to this population

---

GSK plc (LSE/NYSE: GSK) today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has accepted for review a regulatory application to extend the indication of GSK's respiratory syncytial virus (RSV) vaccine (recombinant adjuvanted) for the prevention of RSV disease in adults aged 50-59 at increased risk.

This regulatory submission follows Japan's approval of GSK's vaccine for the prevention of RSV disease in adults from the age of 60 years, and the recent announcement of the positive results of a phase III trial [NCT05590403] evaluating the immune response and safety of GSK's RSV vaccine in adults aged 50-59, including those at increased risk for RSV lower respiratory tract disease (LRTD) due to certain underlying medical conditions.

The burden of RSV disease in adults is likely to be underestimated due to lack of awareness and standardised testing, as well as under-detection within surveillance studies[1], but people with underlying medical conditions – such as chronic obstructive pulmonary disease (COPD), asthma, chronic heart failure[2] and diabetes[3]– are at increased risk for RSV disease. RSV can exacerbate these conditions and lead to pneumonia, hospitalisation, or death.[4] An international systematic review of the prevalence of respiratory viruses in patients with acute exacerbations of COPD, for example, showed that RSV was detected 1 in 10 cases.[5]

GSK is the first company to seek regulatory approval to extend RSV vaccination to help protect adults aged 50 to 59 at increased risk for RSV disease. Further announcements on regulatory progress in the US and EU are expected in early 2024.

About *Arexvy*

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.

The MHLW has approved GSK's RSV vaccine for the prevention of RSV (respiratory syncytial virus) disease for adults aged 60 years and above. 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 lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older in the US, Europe, 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.

Stock-exchange announcement
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.

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 neutralisation titres 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 have been presented at the US Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) meeting on 25 October 2023 and 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[4]. RSV can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death[4]. Each year, RSV causes approximatively 470,000 hospitalisations and 33,000 in-hospital deaths in adults 60 years of age and older in industrialised countries, including approximately 63,000 hospitalisations and 4,500 deaths in Japan[1]. Adults with underlying conditions are more likely to seek medical advice and have higher hospitalisation rates than adults without these conditions[6].

Please refer to the updated Product Information (PI) for important dosage, administration, and safety information in Japan at this link: https://www.info.pmda.go.jp/psearch/html/menu_tenpu_base.html

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)

Stock-exchange announcement
For media and investors only

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, and Q3 Results for 2023.

Registered in England & Wales:
No. 3888792

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

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 2023; 17:e13031
[2] Falsey, AR *et al*. Respiratory syncytial virus infection in elderly and high-risk adults, in *New Engl J Med* 2005; 352:1749-59
[3] Richard Osei-Yeboah *et al*, Respiratory syncytial virus-associated hospitalisation in adults with comorbidities in two European countries, PROMISE investigators, preprint, August 2023
[4] Centers for Disease Control and Prevention (CDC), RSV in Older Adults and Adults with Chronic Medical Conditions, 2023
[5] Zwaans WA *et al*., The relevance of respiratory viral infections in the exacerbations of chronic obstructive pulmonary disease—A systematic review, in *J Clin Virol* 2014;61:181–188
[6] Branche AR *et al*. Incidence of Respiratory Syncytial Virus Infection Among Hospitalized Adults, 2017-2020, *Clin Infect Dis* 2022;74:1004–1011