RNS Number : 6407R
GSK PLC
10 June 2024

Issued: 7 June 2024, London UK

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

- Over 13 million US adults aged 50-59 years have a medical condition that increases their risk of severe RSV outcomes[1]
- Clinical development programme continues to evaluate safety and immunogenicity in adults 18+ with data read-outs expected H2 2024

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved *Arexvy* (Respiratory Syncytial Virus (RSV) Vaccine, Adjuvanted) for the prevention of RSV lower respiratory tract disease (LRTD) in adults 50 through 59 years of age who are at increased risk. In the US, the vaccine is currently approved for use in adults aged 60 and older and recommended by CDC/ACIP using shared clinical decision-making.

A systematic review of studies in the US showed that RSV is estimated to cause 42,000 hospitalisations* each year in adults aged 50-64 years old.[2] Adults with underlying medical conditions, such as chronic obstructive pulmonary disease (COPD), asthma, heart failure and diabetes[3] are at increased risk for severe consequences from an RSV infection compared to those without these conditions. RSV can exacerbate these conditions and lead to pneumonia, hospitalisation or death.[4]

*adjusted for under-detection

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. For those with underlying medical conditions, RSV can have serious consequences, so we are proud to be the first to help protect them from RSV-LRTD."

The regulatory application was supported by positive results from a phase III trial [NCT05590403][5] 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.

Professor Ann R. Falsey, University of Rochester School of Medicine, said: "I am thrilled that GSK's RSV vaccine is now approved for adults aged 50-59 at increased risk of RSV-LRTD. When it comes to the risks associated with RSV, age is just a number, an important number, but not the only factor to consider. Many adults in this age group have underlying health conditions that place them at increased risk for serious illness with RSV infection compared with those without these conditions. Now there is a vaccine approved that can help protect them."

GSK has also filed regulatory submissions to extend the use of its RSV vaccine to adults aged 50-59 at increased risk in Europe, 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 in H2 2024.

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, the FDA 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 vaccine has also been approved for the prevention of RSV-LRTD in individuals 60 years of age and older in over 40 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 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, randomised, multi-country immunogenicity trial to evaluate the non-inferiority of the immune response and evaluate safety in participants aged 50 to 59, including those at increased risk for 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 for 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 at one month after the vaccine administration compared to adults aged 60 and older. There were also safety and immunogenicity secondary and tertiary endpoints. Safety and reactogenicity data were consistent with results from the initial AReSVi-006 data read out. The most common local adverse event was pain. The most common systematic adverse events were myalgia, fatigue and headache, which were largely transient and mild to moderate in intensity.

Results from this trial have been presented at the ACIP meeting of October 2023 and at ReSVinet in February 2024, and have been submitted for peer-reviewed publication. The data 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 is estimated to cause approximately 177,000 hospitalisations in adults 65 years and older[6] and 42,000 in adults aged 50-64 years old in the US[2].

Please see the full US Prescribing Information:
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Arexvy/pdf/AREXVY.PDF

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)

Registered Office:

980 Great West Road

Brentford, Middlesex

TW8 9GS

References

[1] Horn et al, "Disparities in Risk Factors for Severe Respiratory Syncytial Virus Disease among Adults in the United States", Abstract presented at National Foundation for Infectious Diseases - 27th Annual Conference on Vaccinology Research - NFID 2024; May 8-10, 2024

[2] McLaughlin JM et al, "Rates of Medically Attended RSV Among US Adults: A Systematic Review and Meta-analysis" in *Open Forum Infectious Diseases*, Volume 9, Issue 7, July 2022

[3] Branche AR *et al.*, « Incidence of Respiratory Syncytial Virus Infection Among Hospitalized Adults, 2017-2020" in *Clinical Infectious Diseases,* 2022:74:1004-1011

[4] Centers for Disease Control and Prevention (CDC), RSV in Older Adults and Adults with Chronic Medical Conditions, 2024

[5] ClinicalTrials.gov, A Study on the Immune Response and Safety of a Vaccine Against Respiratory Syncytial Virus Given to Adults 50-59 Years of Age, Including Adults at Increased Risk of Respiratory Syncytial Virus Lower Respiratory Tract Disease, Compared to Older Adults 60 Years of Age and Above 2023. NCT05590403.

6 Falsey, AR *et al*. Respiratory syncytial virus infection in elderly and high-risk adults, in *New Engl J Med* 2005; 352:1749-59

END

MSCQKOBQCBKKAAK