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GSK's RSV vaccine, *Arexvy*, accepted for regulatory review by the European Medicines Agency to expand use in adults 18 years and older

- Regulatory decision anticipated H1 2026

GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency (EMA) has accepted the company's regulatory application to expand the use of its adjuvanted recombinant respiratory syncytial virus (RSV) vaccine to include adults from 18 years of age. *Arexvy* was the first RSV vaccine approved in the European Economic Area for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged 60 and older, and for those aged 50-59 years who are at increased risk for RSV disease.

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.[1] RSV can exacerbate certain medical conditions, and lead to severe illness resulting in hospitalisation and even death.[2,3,4]

A European regulatory decision on this submission is anticipated in H1 2026. GSK is continuing to seek expanded indications for its RSV vaccine in other geographies including the US and Japan.

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.

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 been approved for the prevention of RSV-LRTD in individuals 60 years of age and older in more than 60 countries. In addition, it is approved for use in individuals aged 50-59 who are at increased risk due to certain underlying medical conditions in more than 50 markets, including the US, Japan and Europe.

Please refer to the updated Product Information (PI) for important dosage, administration, and safety information in Europe at this link: http://www.ema.europa.eu/medicines/human//EPAR/arexvy

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 RSV in adults
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.[1] Adults can be at increased risk for RSV disease due to certain 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]

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.

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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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q1 Results for 2025.

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Notes:

*The European Medicines Agency reviews medicines for European Union member states, as well as in the European Economic Area (EEA) countries Iceland, Norway and Liechtenstein.

References:

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