Stock-exchange announcement
For media and investors only

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GSK's RSV vaccine, *Arexvy*, receives positive CHMP opinion for all adults 18 years and older

- Marketing authorisation expected in February 2026
- Every year an average of 158,000 adults are hospitalised with RSV-related illness in the EU[1]

GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended expanding the indication of its adjuvanted recombinant respiratory syncytial virus (RSV) vaccine to all adults aged 18 years and older. The European Commission's final decision is expected in February 2026. If approved, the expanded indication would make the vaccine available for all adults aged 18 years and older.*

Arexvy was the first RSV vaccine approved in Europe for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged 60 and older, and in those aged 50-59 years who are at increased risk for RSV disease.

Sanjay Gurunathan, GSK Head of Vaccines and Infectious Diseases Research and Development, said: "Today's positive CHMP opinion is an important step towards bringing more options to prevent severe RSV disease for adults in Europe. GSK is dedicated to increasing access to our vaccines in broader adult populations and we continue to drive innovation to help make it easier for healthcare professionals to offer protection against severe 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.[2] RSV can exacerbate certain medical conditions, and lead to severe illness resulting in hospitalisation and even death.[1,3,4]

In the European Union, an average of 158,000 adults aged 18 and over are hospitalised due to RSV infections each year.[1] Compared with children, adults hospitalised for RSV are at a higher risk of severe complications, require more costly treatments, have a higher fatality rate, and their true number is likely to be underestimated due to lack of routine testing.[5,6,7,8]

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 65 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 55 countries, including the US, Japan and Europe.

Please refer to the 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, owned by GSK, contains STIMULON QS-21 adjuvant licensed from Antigenics Inc, currently dba Agenus Inc. STIMULON is a trademark of SaponiQx Inc., a subsidiary of Agenus Inc.

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.[2] 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 www.gsk.com.

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

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