Stock-exchange announcement
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Arexvy approval expanded to adults aged 50-59 at increased risk of severe RSV disease in Japan

- First RSV vaccine approved in Japan to help protect 50-59 year olds at increased risk due to certain underlying health conditions
- RSV infections can exacerbate these underlying health conditions and lead to severe outcomes, such as pneumonia, hospitalisation and death[1]
- 35 countries, including the US, have expanded approval for GSK's RSV vaccine in this at increased risk population

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GSK plc (LSE/NYSE: GSK) today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved a regulatory application to extend the indication of *Arexvy* (respiratory syncytial virus vaccine, recombinant adjuvanted) for the prevention of RSV disease to include adults aged 50-59 at increased risk. Since September 2023, GSK's RSV vaccine has been approved in Japan for adults aged 60 and over for the prevention of RSV disease.[2]

Tony Wood, Chief Scientific Officer at GSK, said: "This approval reflects our ambition to protect people at increased risk from the severe consequences of RSV infection. Adults aged 50-59 with certain underlying medical conditions can face debilitating consequences from RSV, so we are pleased to offer those in Japan a vaccine for the first time."

RSV is a common contagious virus affecting the lungs and breathing passages and it impacts an estimated 64 million people of all ages globally every year.[3] Adults can be at increased risk for RSV disease due to certain underlying medical conditions, immune compromised status, or advanced age.[1] RSV infection can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death.[1]

This regulatory expansion was supported by results from a global phase III trial (including 4 clinical sites in Japan) that showed non-inferior immunogenicity in adults aged 50-59 at increased risk of RSV lower respiratory tract disease compared to those aged 60 and older.[4] Safety and reactogenicity in the 50-59 at increased risk population were consistent with results from the initial phase III programme in adults aged 60 and older. [4]

To date, GSK's RSV vaccine has been approved for adults aged 50-59 at increased risk in 35 countries, including the US, with regulatory decisions for other geographies undergoing review.

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 September 2023, the MHLW approved GSK's RSV vaccine for the prevention of RSV (respiratory syncytial virus) disease for adults aged 60 years and above in Japan. 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* Product Information, including a full list of adverse events and the complete important safety information in Japan, will be available from the Japan Pharmaceuticals and Medical Devices Agency.

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 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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