Stock-exchange announcement
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GSK's RSV vaccine, *Arexvy*, accepted for regulatory review in China for adults aged 60 years and older

- If approved, *Arexvy* will be the first vaccine available in China for the prevention of lower respiratory tract disease caused by RSV in adults aged 60 and older
- RSV affects over six million people aged 60 and older in China each year[1]

GSK plc (LSE/NYSE: GSK) today announced that its regulatory application for *Arexvy* (Respiratory Syncytial Virus vaccine, [recombinant, adjuvanted]), has been accepted for review by China's Center for Drug Evaluation (CDE) for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults aged 60 years and older. If approved, *Arexvy* will be the first vaccine available to this population in China to help protect against the potentially serious consequences of RSV disease.

The regulatory submission is based on the vaccine's robust data package,[2,3] including positive results from a Phase III trial evaluating the safety and immunogenicity of the vaccine in adults aged 60 years and older in China (NCT06551181).[4,5] All primary endpoints were met and the vaccine has an acceptable safety profile.[4,5] A regulatory decision is expected in 2027.

RSV is estimated to affect more than six million adults aged 60 years and older in China annually, leading to over 350,000 RSV-related hospitalisations.[1]

About GSK's RSV vaccine

Respiratory Syncytial Virus vaccine (recombinant, adjuvanted) contains recombinant RSV glycoprotein F stabilised in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary AS01$_E$ adjuvant before administration.

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 60 countries, including the US and Japan. In the European Economic Area it is approved for adults aged 18 years and older.

The GSK proprietary AS01 adjuvant system contains STIMULON QS-21 adjuvant licensed from Antigenics LLC, a wholly owned subsidiary of Agenus Inc. STIMULON is a trademark of SaponiQx Inc., a subsidiary of Agenus.

About the study NCT06551181

NCT06551181 was a Phase III randomised, controlled, partially blind, immuno-bridging study to evaluate immunogenicity, reactogenicity, safety and the occurrence of RSV-associated respiratory tract illness after administration of a single dose of GSK's RSVPreF3 investigational vaccine in adults aged 60 years and older in China compared to adults aged 60 years and older outside of China. The four co-primary endpoints were measures of non-inferiority of a humoral immune response to the RSV-A & RSV-B strains in adults aged 60 years and older in China compared to adults aged 60 years and older outside of China. The study included around 1,200 participants in the China vaccinated group, around 800 participants in the overseas vaccinated group and around 600 participants in the placebo group (all participants in this latter group were from China). The study was conducted in 41 locations across 7 countries.

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.[6] Adults can be at increased risk for RSV disease due to certain comorbidities, immune compromised status, or advanced age.[7] RSV can exacerbate certain conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death.[7] Compared to children, adults hospitalised for RSV are at a higher risk of severe complications, require more costly treatments, have a higher fatality rate, and the true number of RSV-related cases is likely underestimated due to lack of routine testing.[8,9,10,11]

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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