GSK

Stock-exchange announcement

For media and investors only

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Arexvy, GSK's Respiratory Syncytial Virus (RSV) vaccine, receives positive European Medicines Agency CHMP opinion for adults aged 50-59 at increased risk for RSV disease

- If approved, this will be the first vaccine in the EU for adults aged 50-59 who are at increased risk of respiratory syncytial virus disease
- Decision on EU marketing authorisation for this population expected by September 2024

GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended expanding the approval of GSK's respiratory syncytial virus (RSV) vaccine for the prevention of lower respiratory tract disease (LRTD) caused by RSV from adults aged 60 and above to include adults aged 50-59 years at increased risk for RSV disease.

Today's positive opinion is the first time that an indication for adults aged 50-59 has been recommended by CHMP for a RSV vaccine, one of the final steps prior to the extension of the marketing authorisation by the European Commission. The European Commission's final decision is expected by September 2024. Since June 2023, *Arexvy* (respiratory syncytial virus vaccine, recombinant adjuvanted) has been approved in Europe for adults aged 60 and over for the prevention of RSV-LRTD.

Adults with underlying medical conditions, such as chronic obstructive pulmonary disease (COPD), asthma, heart failure[1] and diabetes[2] 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.[1]

Each year, RSV causes approximately 270,000 hospitalisations and 20,000 in-hospital deaths in adults 60 years of age and older in Europe.[3] The burden of RSV disease in at increased risk adults aged 50-59 is similar to that of the overall population aged 60 and above.[4]

The positive opinion is supported by 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.

GSK's RSV vaccine was approved by the US FDA for adults aged 50-59 at increased risk on 7 June 2024. GSK has also filed regulatory submissions to expand the use of its RSV vaccine to adults aged 50-59 at increased risk in 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 due to certain underlying medical conditions and in immunocompromised adults aged 18 and over are expected to read out in H2 2024.

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.

The vaccine was approved in Europe for adults aged 60 and over for the prevention of RSV-LRTD in June 2023. 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 45 countries, including the 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 RSV in older 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. RSV can exacerbate conditions, including COPD, asthma, and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death.[1] Each year RSV causes approximatively 470,000 hospitalisations and 33,000 deaths in adults aged 60 and older in high-income countries.[3]

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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