GSK’s RSV vaccine, Arexvy, receives European approval for expanded use in all adults 18 years and older

GSK plc, a global biopharma company, announced that its adjuvanted recombinant respiratory syncytial virus (RSV) vaccine, Arexvy, has been approved by the European Commission (EC) for use in adults aged 18 years and older. Arexvy was the first RSV vaccine authorised in the European Economic Area for the prevention of lower respiratory tract disease (LRTD) caused by RSV. It was previously approved in adults aged 60 years and above, as well as in those aged 50 to 59 years who are at increased risk for RSV disease. Today’s updated indication now enables European countries to make the vaccine available to all adults aged 18 years and older.

Sanjay Gurunathan, GSK head of vaccines and infectious diseases research and development, said: “This approval helps protect all adults aged 18 and older in Europe against RSV, a potentially serious respiratory infection that can lead to significant illness, hospitalisation and even death, particularly for those with certain underlying health conditions. GSK is proud to expand prevention options against RSV across Europe.”

In the European Union, an average of 158,000 adults aged 18 and over are hospitalised due to RSV infections each year. 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 their true number is likely underestimated due to lack of routine testing.

GSK continues to seek expanded indications for its RSV vaccine in other geographies including the US and Japan.

Respiratory syncytial virus vaccine, adjuvanted, contains recombinant RSV glycoprotein F stabilised in the prefusion conformation (RSVPreF3). This antigen is combined with GSK’s proprietary AS01E 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 for RSV disease due to certain underlying medical conditions in more than 60 countries, including the US and Japan.

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.

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. Adults can be at increased risk for RSV disease due to certain chronic conditions, immune compromised status or advanced age. RSV can exacerbate certain chronic conditions, including COPD, asthma and chronic heart failure, and can lead to severe outcomes such as pneumonia, hospitalisation and death.

GSK is a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together.

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