GSK’s respiratory syncytial virus older adult vaccine candidate granted Priority Review by US FDA

PUBLISHED NOV 2, 2022
BY GSK

For media and investors only

- US FDA has set a Prescription Drug User Fee Act action date of 3 May 2023

- This is the third major regulatory milestone for the vaccine candidate following acceptance of regulatory submissions in Europe and Japan

- Vaccine candidate has the potential to be the first available to help protect adults aged 60 years and older from lower respiratory tract disease caused by respiratory syncytial virus

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has accepted a Biologics License Application (BLA) and granted Priority Review for its respiratory syncytial virus (RSV) older adult vaccine candidate.

The US FDA grants Priority Review to applications for vaccines that, if approved, would offer significant improvements in the safety or effectiveness of the treatment or prevention of serious conditions when compared to standard applications. A Priority Review designation means the US FDA’s goal is to expedite review of a BLA, reducing the review period by four months. The Prescription Drug User Fee Act date, the FDA action date for their regulatory decision, is 3 May 2023. If approved, GSK’s RSV older adult vaccine candidate has the potential to be the first vaccine available to help protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection.

Older adults are at high risk for severe disease due to age-related decline in immunity and underlying conditions. RSV can exacerbate

conditions, including chronic obstructive pulmonary disease (COPD), asthma and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death.

The BLA is based on positive data from a prespecified interim analysis of the pivotal AReSVi-006 (Adult Respiratory Syncytial Virus) phase III trial, which showed high overall vaccine efficacy against RSV lower respiratory tract disease (LRTD) in adults aged 60 years and older. The vaccine was well tolerated with a favourable safety profile. The most frequent observed solicited adverse events were injection site pain, fatigue, myalgia, and headache. Consistent high vaccine efficacy was observed against LRTD in severe disease, adults aged 70-79 years, adults with underlying comorbidities and across RSV A and B strains.

This is the third major regulatory milestone for GSK’s RSV older adult vaccine candidate following regulatory submission acceptances by the European Medicines Agency and Japan’s Ministry of Health, Labour and Welfare. GSK’s RSV older adult vaccine candidate contains a recombinant subunit prefusion RSV F glycoprotein antigen (RSVPreF3) combined with GSK’s proprietary AS01E adjuvant. There are currently no RSV vaccines for older adults approved anywhere in the world.

About the AReSVi-006 trial

The AReSVi-006 (Adult Respiratory Syncytial Virus) phase III trial is a randomised, placebo-controlled, observer-blind, multi-country trial to demonstrate the efficacy of a single dose of GSK's adjuvanted RSVPreF3 older adult investigational vaccine in adults aged 60 years and above. Approximately 25,000 participants were enrolled from 17 countries.

The GSK proprietary AS01 adjuvant system contains QS-21 Stimulon adjuvant licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc.

RSV is a common contagious virus affecting the lungs and breathing passages. It is one of the major remaining infectious diseases for which there is currently no vaccine or specific treatment available for adults. In adults, RSV infection is typically mild, but may lead to severe outcomes. Older adults are at high risk for severe disease due to age-related decline in immunity and underlying conditions. RSV can

exacerbate conditions, including COPD, asthma and chronic heart failure and can lead to severe outcomes, such as pneumonia, hospitalisation, and death. Each year, RSV causes over 420,000 hospitalisations and 29,000 deaths in adults aged 60 years and older in industrialised countries, including approximately 177,000 and 14,000, respectively in the US. Adults with underlying conditions are more likely to seek medical advice and have higher hospitalisation rates than adults without these conditions.

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/company

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2021, GSK's Q2 Results for 2022, and when issued GSK's Q3 Results for 2022, and any impacts of the COVID-19 pandemic.

Press release distributed by Wire Association on behalf of GSK, on Nov 2, 2022. For more information subscribe and follow us.

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