GSK marketing authorisation application for respiratory syncytial virus older adult vaccine candidate accepted by European Medicines Agency under accelerated assessment

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For media and investors only

- Application based on positive pivotal phase III data showing vaccine efficacy against respiratory syncytial virus-lower respiratory tract disease in adults aged 60 years and above with a favourable safety profile

- This is the second major regulatory milestone for the vaccine candidate following acceptance of a submission in Japan

GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency (EMA) has validated the marketing authorisation application (MAA) for its respiratory syncytial virus (RSV) older adult vaccine candidate.

MAAs may be eligible for accelerated assessment if the EMA's Committee for Medicinal Products for Human Use decides the product is of major interest for public health and therapeutic innovation. A European regulatory decision is anticipated in Q3 2023. If approved, GSK's RSV older adult vaccine candidate has the potential to be the first vaccine available to help protect older adults from RSV lower respiratory tract disease (LRTD).

The MAA 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 LRTD in adults aged 60 years and above. 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 second major regulatory development for GSK's RSV older adult vaccine candidate following Japanese regulatory submission acceptance in October 2022. 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 chronic obstructive pulmonary disease, 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 above in industrialised countries. 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 any impacts of the COVID-19 pandemic.

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