GSK regulatory submission accepted by Japanese regulator for respiratory syncytial virus older adult vaccine candidate

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BY GSK

For media and investors only

- Regulatory submission 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

- Further announcements on regulatory progress in the US and EU are expected in Q4 2022

GSK plc (LSE/NYSE: GSK) today announced that a new drug application for its respiratory syncytial virus (RSV) older adult vaccine candidate has been accepted for review by the Japanese Ministry of Health, Labour and Welfare (MHLW). The proposed indication is for adults aged 60 years and above to prevent lower respiratory tract diseases (LRTD) caused by RSV.

The filing 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, with a favourable safety profile. 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.

Further announcements on regulatory progress in the US and EU are anticipated before the end of 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 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 OA investigational vaccine in adults aged 60 years and above. Approximately 25,000 participants were enrolled from 17 countries.

About respiratory syncytial virus (RSV) in adults

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. 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. Each year, RSV causes over 420,000 hospitalisations and 29,000 deaths in adults in industrialised countries, including approximately 57,000 and 4,000, respectively in Japan. 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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