GSK shares positive data for Arexvy, its respiratory syncytial virus (RSV) older adult vaccine, indicating protection over two RSV seasons

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For media and investors only

- New results from the ongoing AReSVi-006 phase III trial show vaccine efficacy against RSV-lower respiratory tract disease and severe disease over two full RSV seasons, including in participants with underlying medical conditions

- Safety and reactogenicity data were consistent with initial results from the phase III programme

- The clinical development programme will continue to evaluate longer term follow up and the optimal timing for revaccination

GSK plc (LSE/NYSE: GSK) today announced new data from the AReSVi-006 (Adult Respiratory Syncytial Virus) phase III trial evaluating the efficacy of a single dose of Arexvy (respiratory syncytial virus vaccine, adjuvanted) against lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults aged 60 years and older over multiple RSV seasons and after annual revaccination.

Efficacy of a single dose over two seasons

The results show that one dose of the vaccine is efficacious against RSV-LRTD and severe LRTD over two full RSV seasons.

A similar pattern of vaccine efficacy over two seasons was also observed in adults with underlying comorbidities and in advancing age, reinforcing the impact the vaccine could have on those most at

risk of the severe outcomes of RSV.

The trial also evaluated efficacy following an annual revaccination schedule as a confirmatory secondary endpoint. Cumulative efficacy over two seasons in participants who received a second dose of the vaccine was 67.1% (97.5% CI, 48.1-80.0, 30 of 12,469 vs 139 of 12,498), suggesting revaccination after 12 months does not appear to confer additional benefit for the overall population. The clinical development programme will continue to evaluate longer term follow up and the optimal timing for potential revaccination.

Tony Wood, Chief Scientific Officer, GSK, said:

> Our goal is to provide a high level of protection for older adults most at risk from RSV. These data show the efficacy of a single dose of our vaccine over two RSV seasons against RSV-LRTD, including in the populations most at risk due to age or underlying medical conditions. This reinforces our confidence in its potential to make a significant public health impact. We look forward to discussing these results with regulators and vaccine recommending bodies and to collecting more data from the ongoing clinical development programme.

Safety and reactogenicity data were consistent with initial observations from the phase III programme. The vaccine was generally well tolerated. The most frequently observed adverse events were injection site pain, fatigue, myalgia, headache, and arthralgia. These were generally mild to moderate and transient.

GSK will present these data at the US Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) meeting on 21 June 2023. Data from two influenza co-administration trials (quadrivalent high dose and quadrivalent adjuvanted) will also be presented, adding to the seasonal quadrivalent influenza vaccination co-administration data in the current US product label. These data will be submitted to the US Food and Drug Administration (FDA) and other regulators for review.

This is a randomised, placebo-controlled, observer-blind, multi-country phase III trial to demonstrate the efficacy of a single dose of GSK's adjuvanted RSV older adult vaccine over three years and following an annual revaccination schedule in adults aged 60 years and above. Approximately 25,000 participants were enrolled from 17

countries. The trial's primary endpoint was vaccine efficacy against RSV-LRTD after one RSV season. Initial results were published in the New England Journal of Medicine in February 2023.

After the first season, 12,469 participants in the vaccine arm were re-randomized to receive either the RSV vaccine or placebo and were followed up for occurrence of RSV-LRTD. Vaccine efficacy of a single dose against RSV-LRTD after two seasons and vaccine efficacy after annual revaccination were confirmatory secondary endpoints

About Arexvy (respiratory syncytial virus vaccine, adjuvanted)

Respiratory syncytial virus vaccine, adjuvanted, contains recombinant glycoprotein F stabilised in the prefusion conformation (RSVPreF3). This antigen is combined with GSK's proprietary AS01E adjuvant.

The vaccine was approved by the US FDA on 3 May 2023 for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

In June 2023, the European Commission authorised the vaccine for active immunisation for the prevention of LRTD caused by RSV in adults aged 60 years and older. Regulatory reviews in Japan and other counties are ongoing.

The vaccine is not approved anywhere else in the world. The proposed trade name remains subject to regulatory approval in other markets.

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

Please see the full US Prescribing Information:

https://gskpro.com/content/dam/global/hcpportal/en_US/Prescrib... (PDF - 300KB)

RSV is a common contagious virus affecting the lungs and breathing passages. Older adults are at high risk for severe disease due in part to age-related decline in immunity, and older adults with underlying conditions are at even greater risk for severe disease. 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, approximately 177,000 adults 65 years and older are hospitalised in the US due to RSV; an estimated 14,000 cases result in death. 1 For adults 60 and older, data suggest an increased risk for severe RSV infection that can lead to hospitalisation. 2, 3 Adults with underlying conditions are more likely to seek medical services 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 under Item 3.D 'Risk factors" in the company's Annual Report on Form 20-F for 2022, GSK's Q1 Results for 2023 and any impacts of the COVID-19 pandemic.

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