Medicines and Healthcare products Regulatory Agency authorises GSK’s Arexvy, the first respiratory syncytial virus (RSV) vaccine for older adults

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For media and investors only

- Authorisation will help protect adults 60 years of age and older in the UK from RSV disease for the first time

- In the UK, RSV leads to an estimated 14,000 hospitalisations and an estimated 8,000 deaths in adults 60 years of age and older each year

- The authorisation is based on phase III efficacy data in older adults

GSK plc (LSE/NYSE: GSK) today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) has authorised Arexvy (respiratory syncytial virus vaccine, adjuvanted) for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults 60 years of age and older. This is the first time an RSV vaccine for older adults has been authorised for use in Great Britain by the MHRA.

Neale Belson, Senior Vice President, and General Manager UK at GSK said:

> We are very excited by today’s announcement. Our ambition is to help protect adults 60 years of age and older in the UK who are at risk from RSV disease, including those with underlying medical conditions, who drive the majority of RSV hospitalisations. This authorisation for Arexvy means eligible adults can be vaccinated against RSV disease for the first time, reinforcing GSK’s long history of vaccine innovation.

RSV is a common, contagious respiratory virus that leads to an estimated 175,000 GP visits, 14,000 hospitalisations, and 8,000 deaths each year in adults aged 60 years and over in the UK. 1 Recent studies indicate that the burden of RSV disease may be even greater than that of influenza in hospitalised older adults. 2 Those with underlying medical conditions, such as diabetes and chronic heart and lung disease, drive the majority of RSV hospitalisations. 3, 4

The authorisation is supported by data from the pivotal AReSVi-006 (Adult Respiratory Syncytial Virus) phase III vaccine efficacy trial, published in the New England Journal of Medicine. In this trial, there was high overall vaccine efficacy against RSV-LRTD, including in participants with certain underlying medical conditions. 5

The vaccine was generally well tolerated. The most frequently observed solicited adverse events were injection site pain, fatigue, myalgia, arthralgia, and headache. These were generally mild to moderate and transient.

The MHRA's decision follows the European Commission's authorisation of Arexvy on 6 June 2023. GSK's marketing authorisation application in the EU was reviewed under the accelerated assessment mechanism because prevention of RSV illness in the older adult population is considered a major public health interest.

Arexvy was the world's first RSV vaccine for older adults to be approved by the US Food and Drug Administration. Regulatory reviews are ongoing in Japan and several other countries.

About Arexvy (Respiratory Syncytial Virus (RSV) vaccine (recombinant, 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 MHRA has authorised Arexvy for active immunisation for the prevention of LRTD caused by RSV in adults aged 60 years and older. 6 It is also approved in the US and in member states of the European Union and the European Economic Area (EEA)*. 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 proposed trade name remains subject to regulatory approval in other markets.

A clinical trial investigating RSV vaccination in adults aged 50-59, including participants with underlying comorbidities, is fully recruited. Results are expected in 2023, together with additional results from the AReSVi-006 phase III efficacy trial and the AReSVi-004 immunogenicity trial. These trials continue to evaluate an annual revaccination schedule and protection/immunogenicity over multiple seasons following one dose of the RSV vaccine.

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

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 RSVPreF3 vaccine in adults aged 60 years and above. Approximately 25,000 participants were enrolled from 17 countries. Initial results were published in the New England Journal of Medicine in February 2023.

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. Older adults with underlying medical 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. In the UK, RSV leads to an estimated, 175,000 GP visits, 14,000 hospitalisation and 8,000 deaths in adults aged 60 years and over.1 For adults 60 and older, data suggest an increased risk for severe RSV infection that can lead to hospitalisation.

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.

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.

* The European Commission has the authority to approve medicines for European Union member states, as well as in the European Economic Area (EEA) countries Iceland, Norway, and Liechtenstein

Fleming, D.M., Taylor, R.J., Lustig, R.L. et al. Modelling estimates of the burden of Respiratory Syncytial virus infection in adults and the elderly in the United Kingdom. BMC Infect Dis 15, 443 (2015). https://doi.org/10.1186/s12879-015-1218-z Perez SN, et al. Respiratory Syncytial Virus Disease Burden in Community-Dwelling and Long-Term Care Facility Older Adults in Europe and the United States: A Prospective Study | Open Forum Infectious Diseases | Oxford Academic (oup.com). Open Forum Infectious Diseases, Volume 10, Issue 4, April 2023. Centers for Disease Control and Prevention. RSV in Older Adults and Adults with Chronic Medical Conditions. Accessed March 2023. Available at: cdc.gov/rsv/high-risk/older-adults.html Tseng HF, Sy LS, Ackerson B, et al. Severe morbidity and short- and mid- to long-term mortality in older adults hospitalized with respiratory syncytial virus infection. J Infect Dis. 2020;222(8):1298-1310. doi:10.1093/infdis/jiaa361. https://pubmed.ncbi.nlm.nih.gov/32591787/ The New England Journal of Medicine, Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults https://www.nejm.org/doi/10.1056/NEJMoa2209604 Arexvy (Respiratory Syncytial Virus (RSV) vaccine, (recombinant, adjuvanted)) summary of product characteristics (SmPC) July 2023.

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