Japan’s Ministry of Health, Labour and Welfare approves GSK’s Arexvy, the country’s first respiratory syncytial virus (RSV) vaccine for older adults

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For media and investors only

- Arexvy’s approval will help protect adults 60 years of age and older in Japan from RSV disease for the first time, including those living with underlying medical conditions who are most at risk of severe RSV disease

- RSV causes an estimated 63,000 hospitalisations and 4,500 in-hospital deaths in adults 60 years of age and older in Japan each year

- The approval – the first in Asia – is based on a comprehensive phase III programme, which enrolled over 1,000 Japanese participants

GSK plc (LSE/NYSE: GSK) today announced that Japan’s Ministry of Health, Labour and Welfare (MHLW) has approved Arexvy (respiratory syncytial virus vaccine, recombinant adjuvanted) for the prevention of RSV (respiratory syncytial virus) disease for adults 60 years of age and above. This is the first time an RSV vaccine for older adults has been approved in Japan.

Tony Wood, Chief Scientific Officer at GSK, said: "Arexvy is Japan’s first approved RSV older adult vaccine, and is a major advance for public health with the potential to help protect around 43.5 million Japanese people aged 60 and older 1. Following key approvals in the US, EU, UK and Canada earlier this year, today’s authorisation reinforces GSK’s industry-leading vaccine portfolio”.

RSV is a common, contagious respiratory virus 2 that causes an estimated 470,000 hospitalisations and 33,000 deaths each year in

adults 60 years of age and older in industrialised countries, including approximately 63,000 hospitalisations and 4,500 deaths in Japan. 3 Its impact on healthcare systems may further increase as the population ages. Those with underlying medical conditions, such as chronic heart disease, chronic lung disease or diabetes, account for the majority of RSV hospitalisations. 4

The approval has been granted based on data from the pivotal AReSVi-006 (Adult Respiratory Syncytial Virus) phase III vaccine efficacy trial, published in the New England Journal of Medicine. In the trial, the vaccine showed statistically significant and clinically meaningful overall efficacy of 82.6% (96.95% CI, 57.9–94.1, 7 of 12,466 in the Arexvy arm vs 40 of 12,494 in the placebo arm) against RSV-LRTD in adults aged 60 years and older, meeting the primary endpoint. In addition, secondary descriptive endpoints show that efficacy was 94.6% (95% CI, 65.9–99.9, 1 of 4,937 in the Arexvy arm vs 18 of 4,861 in the placebo arm) in older adults with at least one underlying medical condition of interest, such as certain cardiorespiratory and endocrine-metabolic conditions. 5

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

This is the fifth major regulatory approval for Arexvy, building on approvals from the US Food and Drug Administration, the European Commission, and the regulatory authorities in the UK and Canada.

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 MHLW has approved Arexvy for the prevention of RSV (respiratory syncytial virus) disease for adults aged 60 years and above. 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.

Arexvy, the trade name approved in the US, EU/EEA, UK, Canada and Japan, remains subject to regulatory approval in other markets.

The GSK proprietary AS01 adjuvant system contains STIMULON QS-

21 adjuvant licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc. STIMULON is a trademark of SaponiQx Inc., a subsidiary of Agenus.

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.

About respiratory syncytial virus (RSV) in adults

RSV is a common contagious virus affecting the lungs and breathing passages. Older adults are at high 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, RSV causes over 470,000 hospitalisations and 33,000 in-hospital deaths in adults 60 years of age and older in industrialised countries, including approximately 63,000 hospitalisations and 4,500 deaths in Japan. Adults with underlying conditions are more likely to seek medical advice and have higher hospitalisation rates than adults without these conditions.

Please refer to the updated Product Information (PI) for important dosage, administration, and safety information in Japan which will shortly be updated at this link: https://www.info.pmda.go.jp/psearch/html/menu_tenpu_base.html

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, and Q2 Results for 2023 and any impacts of the COVID-19 pandemic.

Statistics Bureau Home Page/Population Estimates Monthly Report

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