US FDA approves GSK’s Arexvy, the world’s first respiratory syncytial virus (RSV) vaccine for older adults

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For media and investors only

- Ground-breaking approval enables adults aged 60 years and older to be protected from RSV disease for the first time

- The approval is based on data from the positive pivotal AReSVi-006 phase III trial that showed exceptional efficacy in older adults, including those with underlying medical conditions, and in those with severe RSV disease

- US launch is planned before the 2023/24 RSV season

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved Arexvy (respiratory syncytial virus vaccine, adjuvanted) for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. This is the first RSV vaccine for older adults to be approved anywhere in the world.

Tony Wood, Chief Scientific Officer, GSK, said:

> Today marks a turning point in our effort to reduce the significant burden of RSV. Arexvy is the first approved RSV vaccine for older adults, expanding GSK’s industry-leading vaccine portfolio, which protects millions of people from infectious diseases each year. Our focus now is to ensure eligible older adults in the US can access the vaccine as quickly as possible and to progress regulatory review in other countries.

RSV is a common, contagious virus that can lead to potentially serious

respiratory illness. It causes approximately 177,000 hospitalisations and an estimated 14,000 deaths in the US in adults aged 65 years and older each year. 1, 2, 3 Older adults, including those with underlying medical conditions such as diabetes and chronic heart and lung disease, are at increased risk of severe RSV illness and drive the majority of RSV hospitalisations. 4

John Kennedy, MD, President, American Medical Group Association (AMGA) added:

> For decades, AMGA and the healthcare community at large have been active in finding ways to increase adult immunisations. As a result, we are pleased that we can now add a respiratory syncytial virus vaccine to providers' options for patient care. With this vaccine, Americans over the age of 60, and particularly those with underlying health conditions like COPD, asthma, or congestive heart failure, will have a vaccine to help protect against potentially serious outcomes from RSV.

The US FDA approval is based on GSK's landmark positive pivotal AReSVi-006 (Adult Respiratory Syncytial Virus) phase III trial data. 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 vs 40 of 12,494) against RSV-LRTD in adults aged 60 years and older, meeting the primary endpoint. In addition, efficacy was 94.6% (95% CI, 65.9–99.9, 1 of 4,937 vs 18 of 4,861) in older adults with at least one underlying medical condition of interest, such as certain cardiorespiratory and endocrine-metabolic conditions. Efficacy against severe RSV-LRTD, defined as an RSV-associated LRTD episode preventing normal, everyday activities, was 94.1% (95% CI, 62.4–99.9, 1 of 12,466 vs 17 of 12,494).

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

In June 2023, the Advisory Committee on Immunization Practices (ACIP) will make recommendations on the appropriate use of the vaccine in the US. The vaccine will be available for older adults before the 2023/24 RSV season, which typically starts ahead of the winter months.

In April 2023, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending the vaccine for the prevention of LRTD caused by RSV in adults aged 60 years and older. A final European regulatory decision is anticipated in the coming months, while regulatory reviews are ongoing in Japan and several other countries.

About Arexvy (respiratory syncytial virus vaccine, adjuvanted)

Respiratory syncytial virus vaccine, adjuvanted, contains a recombinant subunit prefusion RSV F glycoprotein antigen (RSVPreF3) combined with GSK's proprietary AS01E adjuvant.

In the US, Arexvy is indicated for the prevention of RSV-LRTD in individuals 60 years of age and older. GSK's RSV older adult vaccine is not currently approved anywhere outside the US. The proposed trade name remains subject to regulatory approval outside the US.

A clinical trial that aims to expand the population who may benefit from RSV vaccination into 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. Results from two additional influenza vaccine co-administration trials are also expected before the June 2023 Advisory Committee on Immunization Practices (ACIP) meeting.

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. 3 For adults 60 and older, data suggest an increased risk for severe RSV infection that can lead to hospitalisation. 5, 6 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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