GSK’s respiratory syncytial virus older adult vaccine candidate gains positive European Medicines Agency CHMP opinion

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BY GSK

For media and investors only

- Positive opinion advances GSK’s goal to provide the first vaccine to help protect older adults from respiratory syncytial virus disease

- Opinion is supported by data showing the vaccine candidate’s exceptional efficacy in older adults, including those with underlying medical conditions

- Decision on EU marketing authorisation expected by July 2023

GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion by consensus recommending approval of GSK’s respiratory syncytial virus (RSV) vaccine candidate for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged 60 years and older. This is the first time an RSV vaccine candidate for adults has gained a positive opinion, one of the final steps in the marketing authorisation procedure prior to approval by the European Commission.

There are no RSV vaccines or specific treatments currently available for older adults. RSV causes over 270,000 hospitalisations and approximately 20,000 in-hospital deaths in adults aged 60 years and older each year in Europe. 1 If approved, GSK’s candidate has the potential to be the first vaccine available to help protect older adults from RSV disease.

GSK’s marketing authorisation application has been reviewed under accelerated assessment. This applies to products determined by the CHMP to be of major interest for public health and therapeutic

innovation. The European Commission's final decision is expected by July 2023.

The positive opinion is supported by data from the pivotal AReSVi-006(Adult Respiratory Syncytial Virus) phase III vaccine efficacy trial. In the trial, the vaccine candidate showed 82.6% (96.95% CI, 57.9–94.1, 7 of 12,466 vs. 40 of 12,494) overall vaccine efficacy against RSV-LRTD in adults aged 60 years and older, meeting the primary endpoint. 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 endocrino-metabolic conditions. 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.

GSK's RSV older adult vaccine candidate is also under regulatory review by the US Food and Drug Administration, Japan's Ministry of Health, Labour and Welfare, and several other regulatory agencies, with decisions expected in 2023. Additional regulatory submissions will continue throughout this year.

About GSK's RSV older adult vaccine candidate

GSK's RSV older adult vaccine candidate contains a recombinant subunit RSV prefusion F glycoprotein antigen (RSVPreF3) combined with the Company's proprietary AS01E adjuvant. Across multiple trials, the vaccine candidate was generally well tolerated with an acceptable safety profile. The most frequently observed solicited adverse events were injection site pain, fatigue, myalgia, and headache. These were typically mild to moderate and transient. The GSK proprietary AS01 adjuvant system contains QS-21 STIMULON adjuvant licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc.

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 candidate. Results from two additional influenza

vaccine co-administration trials are also expected in H1 2023.

There are currently no RSV vaccines approved anywhere in the world.

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 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 other conditions, including chronic obstructive pulmonary disease, asthma and chronic heart failure and can lead to severe complications, such as pneumonia, hospitalisation, and death. Each year RSV causes over 470,000 hospitalisations and 33,000 deaths in adults aged 60 and above in high-income countries. 1 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.

Savic M, Penders Y, Shi T, Branche A, Pirçon J-Y. Respiratory syncytial virus disease burden in adults aged 60 years and older in high-income countries: a systematic literature review and meta-analysis. Influenza Other Respir Viruses 2022 November 11 (Epub ahead of print). [PMID: 36369772]. Accessed February 2022. Available at: Respiratory syncytial virus disease burden in adults aged 60 years and older in high-income countries: A systematic literature review and meta-analysis - Savic - Influenza and Other Respiratory Viruses - Wiley Online Library

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