Landmark New England Journal of Medicine publication reinforces potential of GSK's respiratory syncytial virus older adult vaccine candidate

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BY GSK

For media and investors only

- First peer-reviewed publication of phase III respiratory syncytial virus vaccine data in older adults, including those with comorbidities who are most at risk

- Expert perspective recognises a new era in vaccine design based on progress in respiratory syncytial virus research

- Vaccine on track to become available in 2023 pending regulatory decisions in the US, EU, and other countries

GSK plc (LSE/NYSE: GSK) today announced the publication of positive phase III trial results for its respiratory syncytial virus (RSV) older adult vaccine candidate in the New England Journal of Medicine. The publication summarises the pivotal efficacy data (previously presented at IDWeek 2022), showing the vaccine candidate met the primary endpoint of vaccine efficacy against RSV-lower respiratory tract disease (LRTD) in adults aged 60 years and above, with a favourable safety profile. In addition, positive vaccine efficacy was observed in participants with comorbidities of interest who are at increased risk of severe outcomes.

RSV is one of the major infectious diseases without a vaccine or specific treatment available for older adults. The accompanying New England Journal of Medicine expert perspective article recognises the significant progress that has been made in RSV vaccine design. GSK is the first company to publish positive peer-reviewed phase III data for an RSV older adult vaccine candidate.

Tony Wood, Chief Scientific Officer, GSK, said:

> Our ambition is to protect the many older adults at risk from RSV disease, including those with underlying health conditions, who account for the majority of severe RSV outcomes. We are delighted to publish these exceptional data in the New England Journal of Medicine. We look forward to making the vaccine available as quickly as possible, pending regulatory decisions, and sharing more data from our ongoing clinical development programme as we work to get ahead of this potentially debilitating virus.

Professor Martinón-Torres, Co-ordinator of the Vaccine Clinical Trials Unit, Instituto de Investigación Sanitaria de Santiago, Spain, and one of the authors on the New England Journal of Medicine publication, added:

> Although RSV often results in mild symptoms, it can have devastating consequences for older adults and has a global burden that can approach that of seasonal influenza. The publication of these important data shows that, for the first time, we are on the cusp of having an effective vaccine that could meaningfully impact public health.

GSK is on track to supply the vaccine candidate ahead of the 2023-24 northern hemisphere RSV season, pending regulatory decisions in the US, EU, Japan, and other countries. A meeting of the US Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee (VRBPAC) to review the Biologics License Application will take place on 1 March 2023. There are currently no RSV vaccines approved anywhere in the world.

RSV clinical development programme

GSK is conducting three additional phase III clinical trials that aim to expand the population who may benefit from RSV vaccination into adults aged 50-59 with underlying comorbidities and to provide further evidence on co-administration with other older adult vaccines.

These are fully recruited, and results are expected in 2023, together with additional data from the AReSVi-006 (Adult Respiratory Syncytial Virus) phase III efficacy trial and the AReSVi-004 immunogenicity trial. These continue to evaluate an annual revaccination schedule and

protection/immunogenicity over multiple seasons following one dose of the RSV vaccine candidate.

NCT05590403 will evaluate the immunogenicity and safety of the vaccine candidate in adults 50-59 years of age, including adults at increased risk of RSV-LRTD, compared to its immunogenicity and safety in adults ≥60 years of age.

NCT05568797 and NCT05559476 will evaluate the vaccine candidate's immunogenicity, safety and reactogenicity when co-administered with adjuvanted and high-dose influenza vaccines in adults aged 65 years and above. These trials build on positive data on the concomitant administration of GSK's RSV older adult vaccine candidate with seasonal quadrivalent influenza vaccination presented at IDWeek 2022.

About GSK's RSV older adult vaccine candidate

GSK's RSV older adult vaccine candidate contains a recombinant subunit prefusion RSV F glycoprotein antigen (RSVPreF3) combined with the Company's proprietary AS01E adjuvant. Across multiple trials, the vaccine candidate was generally well tolerated with a favourable 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.

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 conditions, including chronic obstructive pulmonary disease, 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 deaths in adults 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 in the Company's Annual Report on Form 20-F for 2021, GSK's Q4 Results for 2022 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 6 December 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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