GSK announces positive pivotal phase III data for its respiratory syncytial virus (RSV) vaccine candidate for older adults

PUBLISHED JUN 10, 2022
BY GSK

For investors and media only

Issued: 10 June 2022, London UK - LSE announcement

- First RSV vaccine candidate to show statistically significant and clinically meaningful efficacy in adults aged 60 years and above

- The magnitude of effect observed was consistent across RSV A and B strains, key secondary endpoints and in those aged 70 years and above

- Engagement with regulators to start immediately with anticipated regulatory submissions in H2 2022

GSK plc (LSE/NYSE: GSK) today announced positive headline results from a pre-specified efficacy interim analysis of the AReSVi 006 phase III trial. The interim analysis was reviewed by an Independent Data Monitoring Committee, and the primary endpoint was exceeded with no unexpected safety concerns observed. AReSVi 006 is a phase III trial investigating GSK's respiratory syncytial virus (RSV) vaccine candidate for adults aged 60 years and above.

Dr Hal Barron, Chief Scientific Officer and President, R&D, GSK, said:

> These data suggest our RSV vaccine candidate offers exceptional protection for older adults from the serious consequences of RSV infection. RSV remains one of the few major infectious diseases without a vaccine, and these data have the potential to meaningfully impact the treatment of RSV and may reduce the 360,000 hospitalisations and more than 24,000 deaths worldwide each year. Given the importance of

these data, we plan to engage with regulators immediately and anticipate regulatory submissions in the second half of 2022.

Results from this phase III trial will be presented in a peer-reviewed publication and at an upcoming scientific meeting. The AReSVi 006 trial will continue to evaluate both an annual revaccination schedule and longer-term protection over multiple seasons following one dose of the RSV older adult (OA) vaccine candidate.

GSK's RSV OA vaccine candidate contains a recombinant subunit prefusion RSV F glycoprotein antigen (RSVPreF3) combined with GSK's proprietary AS01 adjuvant. AS01 is used with several of GSK's established adjuvanted vaccines. The antigen plus adjuvant combination may help overcome the natural age-related decline in immunity that contributes to the challenge of protecting older adults from RSV disease.

The AReSVi 006 phase III trial is a randomised, placebo-controlled, observer-blind, multi-country trial to demonstrate the efficacy of a single dose of GSK's adjuvanted RSVPreF3 OA investigational vaccine in adults aged 60 years and above. Approximately 25,000 participants were enrolled from 17 countries.

AReSVi 006 is part of a comprehensive RSV evidence generation programme conducted by GSK. Recent in-house results from a parallel phase III trial, AReSVi 004, investigating the immunogenicity, safety, reactogenicity, and persistence of the vaccine candidate in older adults showed that, in participants aged 60 years and above, one dose of the RSV OA investigational vaccine induced strong humoral and cellular immune responses, which remain above pre-vaccination levels up to at least the six months post-vaccination readout timepoint.

AReSVi 006 is closely monitored for safety, with safety data reviewed internally and by an external Independent Data Monitoring Committee on an ongoing basis.

About respiratory syncytial virus (RSV)

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. Older adults are at high risk for severe disease due to age-related decline in

immunity and underlying conditions. 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 360,000 hospitalisations and 24,000 deaths globally in adults. Adults with underlying conditions are more likely to seek medical advice and have higher hospitalisation rates than adults without these conditions.

GSK is a science-led global healthcare company. For further information please visit www.gsk.com/about-us.

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 GSK's Annual Report on Form 20-F for 2021 and any impacts of the COVID-19 pandemic.

Press release distributed by Wire Association on behalf of GSK, on Jun 10, 2022. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/gsk-announces-positive-pivotal-phase-iii-data-for-its-respiratory-syncytial-virus-rsv-vaccine-candidate-for-older-adults-1846

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk
Website: https://www.gsk.com/
Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK
Twitter - http://twitter.com/GSK
Youtube - http://www.youtube.com/GSK
Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/