Stock-exchange announcement

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GSK announces positive headline data from phase II seasonal influenza mRNA vaccine programme

- A vaccine candidate formulation demonstrated positive A and B strain immune responses relative to standard of care in both younger and older adults
- mRNA platform elicits strong overall antibody titres with an acceptable safety profile
- Data support progression to phase III clinical trials

GSK plc (LSE/NYSE: GSK) today announced positive headline results of a phase II trial (NCT06431607) for its mRNA seasonal influenza vaccine programme. The trial studied a range of mRNA formulations in older and younger adults to evaluate vaccine candidates that could improve immune responses against influenza A and B strains, compared to the current standard of care.

In both younger and older adults, pre-defined success criteria were met. Interim data suggest the vaccine candidates have an acceptable safety and reactogenicity profile for all mRNA formulations tested.

These results build on the previous phase II trial and confirm the mRNA platform elicits strong overall antibody titres with an acceptable safety profile. With these results, the GSK mRNA seasonal influenza vaccine programme will progress into late-stage clinical development.

GSK's Chief Scientific Officer, Tony Wood said: "This marks a significant advancement in our mRNA programme and these data support moving into late-stage development. Ultimately, our goal is to develop a new best-in-class vaccine to bring greater protection to people through the influenza season."

GSK recently signed a new licensing agreement with CureVac to assume full control of developing and manufacturing influenza and COVID-19 candidate vaccines. GSK continues to develop and optimise its mRNA capabilities through investments and partnerships, including in AI/ML-based sequence optimisation, nanoparticle design and manufacturing.

About study NCT06431607

The phase II study assesses the reactogenicity, safety, and immunogenicity of different dose levels of a modified, multivalent vaccine candidate, encoding antigens matched to all three WHO-recommended influenza strains. The study includes 250 healthy younger adults aged 18 to 64 and 250 healthy older adults aged 65 to 85. In each age group, different dose levels were tested in comparison to an age-appropriate, licensed comparator vaccine. https://www.clinicaltrials.gov/study/NCT06431607

About GSK

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.

Press release

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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 GSK's Annual Report on Form 20-F for 2023, and GSK's Q2 Results for 2024.

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