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Issued: September 1 2026, London UK

GSK to advance mRNA seasonal flu vaccine candidate to phase III following positive phase II data

- Results showed higher immune responses versus standard and high dose flu vaccines in younger and older adults respectively[1]
- Vaccine candidate designed to target the two primary surface antigens that cause flu viruses to bind and spread
- Phase III trial to start in September 2026

GSK plc (LSE/NYSE: GSK) presented positive phase II data for its mRNA seasonal influenza (flu) vaccine candidate at the OPTIONS XIII Conference for the Control of Influenza. GSK's vaccine candidate showed higher immune responses against all influenza strains tested compared to licensed standard dose and high dose inactivated flu vaccines in younger and older adults respectively, and was generally well tolerated.[1] Based on these results, GSK intends to start a phase III efficacy trial in September 2026.

This will be the first phase III trial of an mRNA flu vaccine designed to target both haemagglutinin (HA) and neuraminidase (NA), the primary surface antigens that cause the flu virus to bind and spread.[2] While licensed flu vaccines primarily target HA, GSK's vaccine candidate is specifically designed to also target NA. Growing evidence suggests this could help improve protection, illness severity and transmission.[1,3]

Sanjay Gurunathan, GSK Head of Vaccines and Infectious Diseases Research and Development (R&D), said: "These promising data support the potential to better protect people from flu with a vaccine designed to target both HA and NA. With one billion flu cases worldwide each year and up to 650,000 deaths there is a need for next generation vaccine approaches.[4] This result is a significant advance in our cutting-edge mRNA programme, and we look forward to starting phase III imminently."

In July 2026, the US Food and Drug Administration (FDA) granted the vaccine candidate Fast Track designation for the targeted age indication, reflecting the urgent need to improve flu protection.[4]

About the Flu-028 phase II trial
Flu-028 is a randomised, observer-blind phase II trial assessing the immunogenicity and safety of mRNA-based multivalent seasonal flu vaccine candidates in 971 adults 18 years of age and older. Adults 18–64 and ≥65 years of age received different dose levels of either FLUm3HA.b-3NA (encoding an optimised B-strain HA), FLUm3HA-3NA (encoding non-optimised B/HA) or licensed age-appropriate comparators. Immunogenicity and reactogenicity/safety data up to day 181 post-vaccination were assessed.[1]

Previous studies highlighted the gaps in flu vaccination, including the role of NA and the need to improve B-strain HA immunogenicity.[5,6] In the Flu-028 phase II trial, GSK's FLUm3HA.b-3NA flu vaccines demonstrated robust immune responses to HA and NA from influenza A and B strains in younger and older adults.[1] Reactogenicity and safety profiles of the vaccines were acceptable.[1] Based on the results, GSK will further investigate the optimised B-strain HA (FLUm3HA.b-3NA) candidate in a phase III efficacy trial.

About GSK's mRNA seasonal flu vaccine candidate
GSK's investigational mRNA seasonal flu vaccine programme is designed to target haemagglutinin (HA) and neuraminidase (NA).[1] It is part of GSK's respiratory vaccines research and ongoing work to explore new approaches to seasonal flu prevention. GSK's investigational mRNA seasonal flu vaccine candidate is not approved anywhere in the world.

About seasonal flu

Seasonal flu is a contagious respiratory infection that remains a significant global public health challenge, causing substantial illness every year and placing considerable pressure on healthcare systems.[4] Seasonal influenza causes around one billion cases globally each year, including up to 5 million cases of severe illness and up to 650,000 respiratory deaths.[4] Those at increased risk include older adults, pregnant women and people with underlying health conditions. Although vaccination remains the cornerstone of flu prevention, a significant burden of disease still exists, reinforcing the need for continued research into approaches that may improve protection.[4]

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 www.gsk.com.

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