Press release
For media and investors only

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GSK to submit label update for Wellcovorin (leucovorin) at US FDA's request

GSK plc (LSE/NYSE: GSK) confirmed today that it will submit a supplemental New Drug Application (sNDA) for Wellcovorin (leucovorin) to update the label to include an indication for the treatment of cerebral folate deficiency (CFD), a rare disorder. The US Food and Drug Administration (FDA) requested GSK take this action as part of the agency's initiative to investigate opportunities to repurpose older medications for the treatment of chronic diseases.

GSK is supporting this initiative as the NDA holder by adding data from case reports identified by the FDA of genetically confirmed CFD into the US prescribing information for Wellcovorin. GSK does not manufacture or market leucovorin, which is available in generic formulations in the US.

GSK is collaborating with the FDA to request a label update for this medicine as quickly as possible.

About cerebral folate deficiency
Cerebral folate deficiency is a disorder characterized by low concentrations of 5-methylterahydrofolate (5- MTHF) - the active form of folate - in the cerebrospinal fluid, that may manifest with a range of neuropsychiatric symptoms.

About leucovorin
In the US, leucovorin is indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of folic acid antagonists. GSK marketed leucovorin under the brand name Wellcovorin from 1983 to 1997. Leucovorin is now available in the US as a generic drug.

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.

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Cautionary statement regarding forward-looking statements

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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 “Risk Factors” section in GSK’s Annual Report on Form 20-F for 2024, and GSK’s Q2 Results for 2025.

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