FDA approves combination meningococcal vaccine

REUTERS

The U.S. Food and Drug Administration approved British drugmaker GSK's combination vaccine to protect against meningococcal infection for use in people aged 10 through 25 years, the company said on Saturday.

Meningococcal infections, caused by bacteria called Neisseria meningitidis, can lead to severe, sometimes deadly, bloodstream infections as well as severe swelling in the brain and spinal cord.

The vaccine, branded as Penmenvy, combines the immune response-generating components of two of the company's approved vaccines, Bexsero and Menveo, to protect against the five most common strains of meningococcal bacteria, GSK said in a statement.

In 2023, there were 438 confirmed and probable cases of meningococcal disease reported in the United States, according to the Centers for Disease Control and Prevention.

Cases of meningococcal disease have increased sharply since 2021, now exceeding pre-pandemic levels in the U.S., the CDC says.

'Having a combined vaccine which will offer these vaccines in one injection can simplify the vaccination, which can help improve vaccination rate,' said Patty Sabey, a pediatrician with Stanford Medicine Children's Health.

It could also help reduce the risk of long-term complications like brain damage and hearing loss that arise from the infection, Sabey said.

The vaccine's approval was based on data from a late-stage study involving about 3,650 participants aged 10 to 25, which showed that the combination vaccine was as effective as Bexsero and Menveo in protecting against the common strains of meningococcal bacteria, GSK said.

The vaccine was well tolerated, with a safety profile consistent with Bexsero and Menveo, the study showed. The pentavalent vaccine targets the five most common bacterial strains causing the infection – Men A, B, C, W and Y.

Bexsero is approved for the prevention of invasive meningococcal disease caused by Neisseria meningitides serogroup B. Menveo is approved in over 60 countries and protects against meningococcal groups A, C, W and Y.

The FDA approved Pfizer's vaccine Penbraya in 2023, the first shot to protect against five meningococcal bacteria groups.

However, the European Medicines Agency withdrew the marketing authorization for Penbraya in January at Pfizer's request. The company told the agency it would not market the product in the European Union for commercial reasons.

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