US FDA expands GSK's RSV vaccine approval to adults aged 50 to 59

In April, Pfizer said its vaccine succeeded in a trial evaluating it in adults under age 60, adding that it plans to submit for expanded approval of the vaccine in adults aged 18 to 59.

By Sriparna Roy and Christy Santhosh

London: The U.S. Food and Drug Administration approved the expanded use of GSK's respiratory syncytial virus (RSV) vaccine on Friday in adults aged between 50 and 59, making it the first shot endorsed for that age group.

The shot, branded Arexvy, and vaccines from rivals Pfizer and Moderna are already approved for people aged 60 and older for the virus.

RSV, which typically causes cold-like symptoms, is a leading cause of pneumonia in toddlers and older adults, causing 177,000 hospitalizations and 14,000 deaths in the United States annually.

Arexvy has dominated the U.S. RSV vaccine market since its launch last year, outperforming sales of rival Pfizer's Abrysvo to wrest a two-thirds market share in the first quarter.

Moderna's vaccine was approved last month.

The U.S. Centers for Disease Control and Prevention (CDC) is yet to sign off on the use of GSK's vaccine in the expanded patient population.

CDC's panel of independent experts will convene between June 26 to 28.

The drugmaker expects to add 13 million individuals to the shot's eligible pool with the approval.

GSK sees 3 billion pounds ($3.82 billion) in peak annual sales from Arexvy over time.

The company doesn't expect any particular insurance barriers for people 50-59, as under the Affordable Care Act, people will be reimbursed for the shot, Leonard Friedland, director, scientific affairs and public health, vaccines at GSK said.

Arexvy contributed 1.2 billion pounds in sales in 2023, while Pfizer's Abrysvo garnered $890 million.

Morningstar analyst Damien Conover said GSK's vaccine will retain the lion's share of the over $5-billion-a-year market versus Pfizer.

In April, Pfizer said its vaccine succeeded in a trial evaluating it in adults under age 60, adding that it plans to submit for expanded approval of the vaccine in adults aged 18 to 59.

GSK also plans to release data from a trial in adults aged 18 to 49 in the second half of 2024.

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