US FDA approves Pfizer's RSV vaccine for adults at increased risk of the disease

In June, the U.S. CDC narrowed its recommendation for the use of respiratory syncytial virus vaccines in older adults this year and held off on recommending their use for adults under age 60.

Bengaluru: The U.S. Food and Drug Administration on Tuesday approved Pfizer's RSV vaccine for the prevention of lower respiratory tract disease caused by RSV in adults aged 18 to 59 at increased risk of the disease.

In June, the U.S. CDC narrowed its recommendation for the use of respiratory syncytial virus vaccines in older adults this year and held off on recommending their use for adults under age 60.

The CDC has now recommended the use of RSV vaccines in adults aged 75 years or older, and those aged 60-74 who are at increased risk for severe RSV disease.

While the FDA approval is a necessary step, the CDC also needs to recommend the shots before they are available for the age group.

The approval for the vaccine, Abrysvo, in adults aged 18 to 59 was based on the results from a late-stage trial in which two doses of the vaccine were tested in immunocompromised adults aged 18 and older.

The vaccine was well-tolerated and showed a safety profile consistent with findings from other studies of the vaccine, Pfizer said.

CDC's advisers are expected to discuss Pfizer's data at a meeting later this week, but are not expected to vote on whether to expand the recommendation.

Pfizer's vaccine is currently approved for people aged 60 and older as well as for women during the middle of the third trimester of pregnancy to protect their babies.

RSV typically causes cold-like symptoms, but it is also a leading cause of pneumonia in toddlers and older adults, leading to 177,000 hospitalizations and 14,000 deaths in the United States annually.
(Reporting by Sneha S K; Editing by Alan Barona)

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