US FDA approves gradual dosing for Lilly Alzheimer's drug

Lilly presented study data last year showing that after 24 weeks of treatment, 24 per cent of patients given the standard Kisunla regimen experienced a side effect called ARIA-E, a kind of brain swelling, compared with 14% of those on more gradual dosing.

London: The U.S. Food and Drug Administration approved changing the prescribing information for Eli Lilly's Alzheimer's drug Kisunla to allow more gradual dosing to lower the risk of a potentially dangerous type of brain swelling, the company said on Wednesday.

Kisunla, given as a monthly infusion, is part of a class of drugs designed to clear an Alzheimer's-related protein called beta amyloid from the brain. It was approved by the FDA just over a year ago for adults with early-stage Alzheimer's after a study showed it slowed progression of memory and thinking problems by 29% compared with a placebo.

The FDA placed its strongest "boxed" safety warning on Kisunla's prescribing label, flagging the risk of potentially life-threatening brain swelling and bleeding.

Lilly presented study data last year showing that after 24 weeks of treatment, 24% of patients given the standard Kisunla regimen experienced a side effect called ARIA-E, a kind of brain swelling, compared with 14% of those on more gradual dosing.

The altered schedule did not compromise Kisunla's ability to reduce amyloid brain plaques, the company said.

The new dosing recommendation is to start with a single vial, adding a vial each month until reaching the full four-vial dose at month four. The previous schedule was for two vials monthly until moving to the full dose at month four.

"The update will help healthcare professionals in their evaluation of treatment options for patients and their benefit/risk discussions," said Dr. Brandy Matthews, Lilly's vice president for global and U.S. medical affairs for Alzheimer's disease.

Kisunla competes with Eisai and Biogen's amyloid-lowering drug Leqembi, which also carries a boxed warning about safety risks including ARIA-E.

Adoption of the drugs has been slow due to the complexities involved with their use, including the need for extra diagnostic tests and regular brain scans to monitor for side effects.

Both Kisunla and Leqembi are currently being studied for treating people diagnosed with Alzheimer's who have not yet begun to show symptoms of the brain disease.

More than 6 million Americans have Alzheimer's disease, according to the Alzheimer's Association

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