FDA approves at-home starter dose of Eisai-Biogen Alzheimer's drug

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Bengaluru: The U.S. FDA on Monday approved an at-home starting dose of Eisai's and Biogen's Alzheimer's drug, allowing some patients to begin therapy with injections administered by themselves or a caregiver. Shares of Biogen were up 4.5% in afternoon trading.

The approval applies to an under-the-skin formulation of the drug branded as Leqembi.

Until now, patients starting treatment received the drug through intravenous infusions, typically given at a clinic, and could later switch to maintenance treatment after 18 months.

Leqembi's at-home subcutaneous approval could increase uptake by improving patient access and differentiating it from Eli Lilly's Kisunla, which requires intravenous infusions, said BMO Capital Markets analyst Evan Seigerman.

Leqembi is already authorized for adults with Alzheimer's disease, a progressive brain disorder that affects memory, thinking and daily function. The drug targets amyloid beta, a protein that forms plaques in the brains of people with the disease.

The injectable version, called Leqembi IQLIK, can cause reactions at the injection area, including redness, swelling, rash, pain or bruising, the Food and Drug Administration said.

The FDA's decision was based on two earlier trials showing the IV version of Leqembi was effective in patients with early Alzheimer's disease, including those with mild cognitive impairment or mild dementia and confirmed amyloid buildup in the brain.

The regulator said the subcutaneous version was not tested in separate large trials measuring patient outcomes. Instead, it relied on findings showing it produced equivalent results and similar reductions in amyloid plaques compared with the infused version.

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