Experimental Alzheimer's drug shows promise in injected-at-home form

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An experimental version of Eisai Co's Alzheimer's drug that might be given in patients' homes exceeded the power of Leqembi, its approved infused formulation, in an early study that could pave the way to

bolstering uptake.

After six months of treatment, an injected form of the drug cleared 14% more amyloid, a toxic protein linked to Alzheimer's, than its infused counterpart that's now on the market, according to company research presented Wednesday at a conference in Boston. Rates of key side effects—brain swelling and bleeding—were similar with both versions, Tokyo-based Eisai said.

The first drug clearly shown to slow the course of Alzheimer's disease, Leqembi must be intravenously infused at a hospital or center every two weeks. That can be a barrier to using the medication for Alzheimer's patients who may need a caregiver to take them to appointments. Bloomberg Intelligence analysts have said they expect a slow rollout for the drug, which was fully approved in July in the U.S.

Eisai and its partner Biogen Inc. are looking to capture market share before a competing product from Eli Lilly & Co. gains clearance. Currently under regulatory review, Lilly's donanemab is infused just once a month. It removes amyloid quickly, and some patients may be able to stop therapy after about a year.

Eisai's injected version of Leqembi could potentially be given at home in two shots every week. The company's ongoing study compared 72 patients who received injections of the new formulation to 322 who got infusions of Leqembi. The study didn't compare the two versions' cognitive effects.

If the results hold up over the full 12 months of the trial, Eisai hopes to apply for U.S. approval of the injected formulation by the end of March 2024, a spokesperson said. Some doctors at the Clinical Trials on Alzheimer's Disease conference in Boston expressed cautious optimism that the new version Leqembi would be a difference-maker.

At the conference, researchers also presented data from a subset of patients from an earlier large data set that led to approval of Eisai's drug in July, The analysis focused on a group of milder patients with low levels of another Alzheimer's-associated protein called tau in their brains. In that group, roughly 60% of patients who received Leqembi improved after 18 months on the drug, compared to just 28% of low-tau patients on placebo.

The finding, while highly preliminary, had doctors at the conference buzzing as it hinted that drugs like Leqembi just might be able to halt the disease if given early enough in its course. Eisai already has a big trial underway aimed a showing whether Leqembi can prevent Alzheimer's.

Doctors were also excited about the prospects for an injected formulation of Leqembi. "It's a big deal, if it works," Paul Newhouse, director of the Center for Cognitive Medicine at Vanderbilt University Medical Center, said in an interview before Eisai's presentation. If not at home, the injection could be given at a local doctor's office, rather than requiring patients to travel long distances to an infusion center, he said.

"That is a huge benefit for patients," said Newhouse, who has administered Leqembi in research studies for years, as it may reduce the financial and logistical impact.

Vanderbilt is still in the process of setting up a clinical infusion program for the drug, he said.

Even in a convenient, injectable version, treatment with Leqembi still won't be simple. Patients must get specialized PET brain scans to detect amyloid to see if they qualify for the drug. They also must have MRI scans during the course of treatment to monitor for side effects.