FDA approves new drug to treat Alzheimer's disease

July 2 2024, by Robin Foster

A new drug to treat Alzheimer's disease was approved by the U.S. Food and Drug Administration on Tuesday.

In clinical trials, donanemab (Kisunla) modestly slowed the pace of thinking decline among patients in the early stages of the memory-robbing disease. But it also carried significant safety risks, including swelling and bleeding in the brain.

"Kisunla demonstrated very meaningful results for people with early symptomatic Alzheimer's disease, who urgently need effective treatment options. We know these medicines have the greatest potential benefit when people are treated earlier in their disease, and we are working hard in partnership with others to improve detection and diagnosis," Anne White, executive vice president and president of Lilly Neuroscience, said in a company news release announcing the approval. "Each year, more and more people are at risk for this disease, and we are determined to make life better for them."

Alzheimer's advocates applauded the approval.

"This approval marks another step forward in evolving the standard of care for people living with Alzheimer's disease that will ultimately include an arsenal of novel treatments, providing much needed hope to the Alzheimer's community," Dr. Howard Fillit, co-founder and chief science officer at the Alzheimer's Drug Discovery Foundation, said in the Lilly news release. "Diagnosing and treating Alzheimer's sooner than we do today has the potential to meaningfully slow disease progression, giving patients invaluable time to maintain their independence for longer."

Kisunla is similar to another drug, Leqembi, approved to treat Alzheimer's last year. Both attack amyloid protein, which is involved in the development of Alzheimer's, and both slowed dementia by several months. Leqembi is given every two weeks, while Kisunla is given monthly as an intravenous infusion.

Kisunla has another significant difference that will likely appeal to patients and doctors alike: The drug can be stopped once it clears all of the amyloid plaques from the brain.

"Once you've removed the target that you're going after, you then can stop dosing," said White, adding that this could cut the cost and inconvenience of the treatment as well as the risk of side effects.

In the company's trial, 17% of patients receiving donanemab were able to discontinue the drug at six months; 47% stopped within a year; and 69% stopped within 18 months. Importantly, their cognitive decline continued to slow even after they stopped.

Still, the treatment won't come cheap: The list price for Kisunla will be $32,000 a year. Leqembi costs $26,000 per year, but it is continued after all amyloid is cleared.

About one-fourth of those on donanemab experienced swelling or bleeding in the brain. While most of the cases were mild, roughly 2% were serious, and the side effects were linked to three patients' deaths.

With both drugs, patients at higher risk include those who have had more than four microscopic bleeds in the brain and those with an Alzheimer's-linked gene variant called APOE4—especially if they have two copies of the variant, the The New York Times reported.

Some experts worry that emphasis on anti-amyloid drugs might discourage patients from participating in trials for treatments that could be better.

"For the field generally, I think this is moving sideways, and it's slowing progress," Dr. Michael Greicius, a neurologist at Stanford University School of Medicine, told the Times.

Dozens of other drugs are in clinical trials for Alzheimer's, including drugs attacking important features like tau tangles and neuroinflammation, the Times reported.

More information: The Alzheimer's Association has more on Alzheimer's drugs.

Citation: FDA approves new drug to treat Alzheimer's disease (2024, July 2) retrieved 2 July 2024 from https://medicalxpress.com/news/2024-07-fda-drug-alzheimer-disease.html