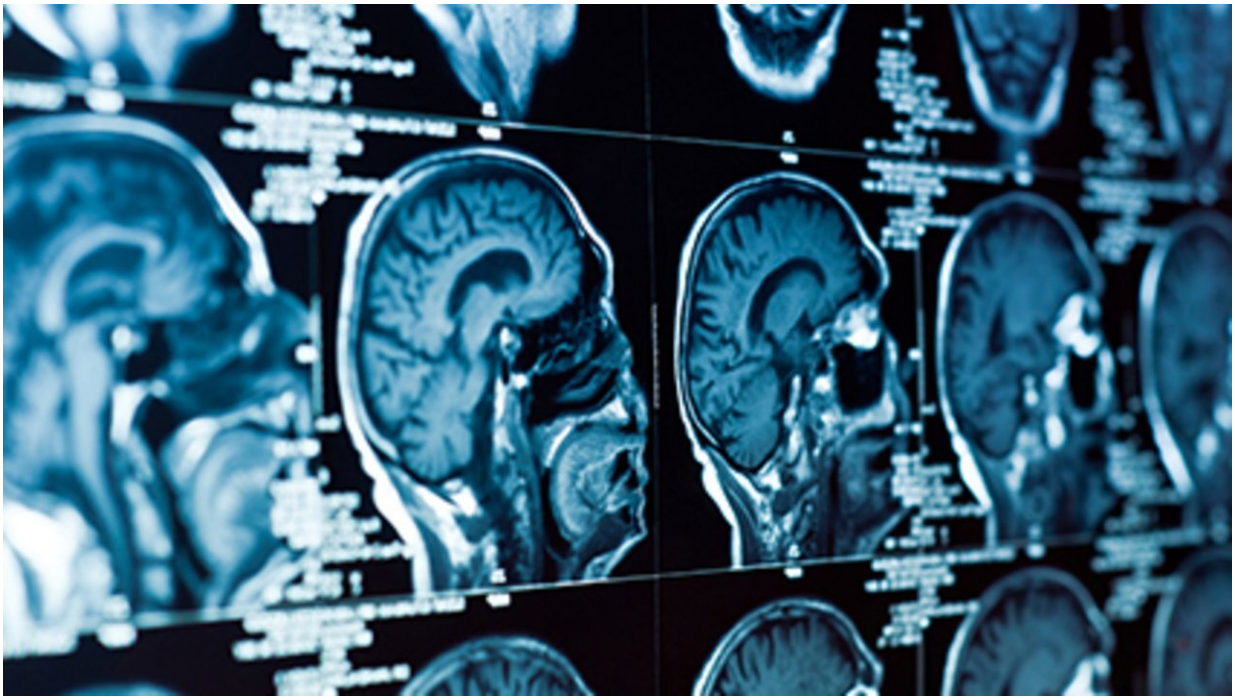
FDA delays decision on new Alzheimer's drug

March 8 2024, by Robin Foster



Instead of approving the new Alzheimer's drug donanemab this month, as was expected, the U.S. Food and Drug Administration will now require the experimental medication be scrutinized more closely by an expert panel, the drug's maker said Friday.

"The FDA has informed Lilly it wants to further understand topics

related to evaluating the safety and efficacy of donanemab, including the safety results in donanemab-treated patients and the efficacy implications of the unique trial design," the company said in a statement.

The move surprised the company, which had believed the agency would give its blessing to the drug during the first quarter of this year.

"We were not expecting this," Anne White, a Lilly executive vice president and president of its neuroscience division, told the Times.

While independent FDA advisory committees are often called upon when the agency has questions about drugs, it was unusual to do so "at the end of the review cycle and beyond the action date that the FDA had given us," White noted.

While the FDA did not comment on the news, Lilly officials said they expected it would be a few months before the appropriate advisory committee meets to weigh the benefits of the drug, the Times reported.

"The FDA did commit to us to move quickly, so we would hope that they would then take action shortly after the advisory committee," White added.

For decades, one experimental Alzheimer's drug after another has been disappointing. However, donanemab, which is given by infusion once a month, belongs to a new class of medications that attack amyloid plaques , a hallmark of the disease.

Last year, another drug in the class, Leqembi, was approved by the FDA. An infusion given every two weeks, Leqembi can modestly slow cognitive decline in the early stages of Alzheimer's.

Still, the new drugs may not slow decline enough to matter to patients or

families, experts said. Not only that, they also carry significant side effects, including swelling and bleeding in the brain.

Donanemab was expected to win approval because data showed that the drug could modestly slow cognitive decline in people with mild symptoms and the safety risks were similar to Leqembi's side effects.

Donanemab's trial had two unique features the FDA will likely ask the advisory committee to evaluate, Dr. John Sims, a medical director with Lilly and the leader of the donanemab clinical trials, told the Times.

One feature was that even after patients stopped receiving donanemab (after amyloid plaques were cleared to a certain level), slowdowns in cognitive declines still continued.

White noted that among doctors and patients, "there's a lot of enthusiasm for this concept of once you clear the target that you're going after, that you don't need to put patients through additional infusions and visits."

The other unusual feature of the trial involved another protein, tau, which forms tangles in the brain after amyloid accumulates. Participants were divided into groups with high tau levels and intermediate tau levels.

What did they find?

People with intermediate tau levels had more slowing of thinking decline, a finding that suggests that intervening early (when tau levels are still relatively low) is the best way to fight Alzheimer's disease.

More information: The U.S. Centers for Disease Control and Prevention has more on Alzheimer's disease.