Three FDA advisers quit over agency approval of aduhelm

June 14 2021

Three members of a U.S. Food and Drug Administration advisory

committee have resigned after the agency this week approved a new drug for Alzheimer disease despite a lack of strong proof that it provides any benefits to patients.

Aduhelm (aducanumab)—a monthly infusion priced at $56,000 per year—is the first treatment for Alzheimer disease approved by the FDA in 18 years, and its approval was pushed by patient advocacy groups because there are only five other treatments available, *The New York Times* reported. Drug maker Biogen plans to begin distributing the drug in about two weeks and expects more than 900 sites nationwide to soon be ready to administer it.

However, none of the 11 members of the FDA advisory committee that reviewed the new treatment considered the drug ready for approval. Ten voted against approval and one was uncertain, *The Times* reported. The FDA is not required to follow its advisory committees' recommendations. The committee said there was no conclusive evidence that Aduhelm could slow mental decline in people in the early stages of Alzheimer disease and noted that it could cause potentially serious side effects of brain swelling and brain bleeding.

Joel Perlmutter, M.D., a neurologist at the Washington University School of Medicine in St. Louis, was the first to resign from the advisory committee after the FDA approved Aduhelm. "Approval of a drug that is not effective has serious potential to impair future research into new treatments that may be effective," he said, *The Times* reported. "In addition, the implementation of aducanumab therapy will potentially cost billions of dollars, and these dollars may be better spent in either developing better evidence for aducanumab or other therapeutic interventions."

For months, several experts, including some involved in the drug's clinical trials, have said the available evidence about Aduhelm raises

significant doubts about its effectiveness. They also suggested that even if it achieves the claimed benefit of slowing the symptoms of Alzheimer disease for about four months over 18 months, that might be barely noticed by patients and would not outweigh the risks for brain side effects, *The Times* reported.

"FDA has determined that there is substantial evidence that Aduhelm reduces amyloid beta plaques in the brain and that the reduction in these plaques is reasonably likely to predict important benefits to patients," Patrizia Cavazzoni, M.D., the agency's director of the Center for Drug Evaluation and Research, wrote on the FDA website about the decision to approve the drug under the accelerated approval program.

More information: *The New York Times* Article

Copyright © 2021 HealthDay. All rights reserved.

Citation: Three FDA advisers quit over agency approval of aduhelm (2021, June 14) retrieved 5 February 2023 from https://medicalxpress.com/news/2021-06-fda-agency-aduhelm.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.