What to Know About the Alzheimer Drug Aducanumab (Aduhelm)

What Should I Know About Alzheimer Disease?
Alzheimer disease is the most common cause of memory loss and dementia in older adults. It is progressive and can have a major negative effect on quality of life and independence.

How Is Alzheimer Disease Diagnosed and Currently Treated?
Diagnosis is based on evaluations that include tests of memory, problem-solving, attention, and language skills. Exercise, brain-stimulating activities, and occupational/cognitive behavioral therapy may help limit progression. Two US Food and Drug Administration (FDA)-approved drugs (donepezil and rivastigmine) may slightly slow symptom progression in those with mild disease. Evidence about long-term effects on thinking, behavior, or independent living is insufficient. No known treatments reverse Alzheimer disease.

What Is Aducanumab?
The FDA recently approved aducanumab (Aduhelm) for people with mild symptoms of Alzheimer disease, such as individuals who are still independent in basic daily functioning. It reduced brain amyloid plaque (protein deposits), a main feature of Alzheimer disease. Plaque reduction, however, has not been a reliable marker for cognitive function in past trials. Not everyone with plaques has or will get Alzheimer disease, and other plaque-reducing medications have not shown meaningful patient benefit.

What Are Potential Benefits of Aducanumab?
Two clinical trials tested aducanumab. When analyzed together, they showed no change in remembering, learning, reasoning, or functioning vs placebo. Examined separately, 1 trial showed slightly less worsening on these measures in patients receiving the drug vs placebo. The average effect seen in the trials is not likely to be noticeable for many patients or families.

What Are Potential Harms of Aducanumab?
Adverse effects were common. In the trials, 41% of patients experienced brain swelling or bleeding. While most cases were mild and managed with dose reduction, 1% to 2% of patients required hospitalization or had long-lasting impairment. A recent patient death linked to aducanumab is under investigation.

How Is Aducanumab Administered?
Aducanumab is given in monthly intravenous infusions in a clinic or hospital. Ideal treatment duration is unknown. Patients need brain scans before treatment and after 6 and 12 months to monitor for brain swelling and bleeding and if new symptoms occur.

What Is the Bottom Line?
Aducanumab does not cure or reverse Alzheimer disease. In 2 clinical trials, after 18 months it reduced amyloid plaque levels, but that did not translate to any clinical effect in 1 trial or a noticeable effect in the other. Potentially serious harms are common. The FDA has required that another trial be completed by 2030 to decide whether aducanumab has a meaningful patient benefit.

For More Information:
- Drug facts box summarizing the main aducanumab trials: https://lisaschwartzfoundation.org/drug-fact-boxes
- FDA labeling and medication guide: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761178s005lbl.pdf

Additional Information:
- This Patient Page is dedicated to the memory of Lisa Schwartz, MD, MS who codeveloped the drug facts box approach.
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