South Florida Hospital News and Healthcare Report
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FDA Approves Aducanumab for Treatment of Alzheimer's Disease

Last month, Aducanumab (Aduhelm™) was approved as a treatment for Alzheimer's Disease by the U.S. Food and Drug Administration (FDA). This is the first FDA-approved therapy to potentially delay decline from the disease, compared to current medications that only address symptoms.

Alzheimer's Disease affects 7.8 million American adults age 65 and older, according to the Alzheimer's Association. That number is expected to rise to more than 12 million by 2050, according to the latest projections from Alzheimer's

Association and dementias affecting people age 65 or older.
While other drugs relieved some symptoms of the condition, Aducanumab has been found in one clinical trial to actually reduce the size of the plaques associated with Alzheimer's in patients with early stages of the disease.
Dr. Barry Baumel, a neurology specialist with University of Miami Neurology Department, calls the FDA approval very significant.

"It's the first drug considered to be a disease modifier to ever be approved for Alzheimer's Disease," he says. "This means it impacts the way the disease progresses. In this case, it slows the progression of the disease, so people hopefully stay better, longer."
Aducanumab removes amyloid from the brain which may delay decline in people who are living with Alzheimer's.
"The drug is an antibody for amyloid," says Dr. Baumel. "It attaches to the amyloid in the brain, removes and disposes it through the body."
According to the FDA, Biogen researchers evaluated the drug's efficacy in two different studies that looked at almost 3,500 patients. Both were "double-blind, randomized, placebo-controlled, dose-ranging studies" in patients living with Alzheimer's disease.
In the clinical trials, Aducanumab reduced the amount of plaque in the brain, according to Dr. Baumel.
This could mean more time for people with Alzheimer's to actively participate in daily life, have sustained independence and hold on to their memories longer.
"They should expect to preserve more of their function for a longer period of time," says Dr. Baumel.
Aducanumab is administered intravenously (IV) via a 60-minute

infusion every four weeks. The infusion, which takes about an hour, can be done at an infusion therapy center by specialized nurses. An MRI will be required within a year of beginning therapy and every six months after that.

In clinical trials, the most common side effects were ARIA-E (abnormal brain changes associated with anti-amyloid treatments – most often swelling in the brain – that are spotted with neuroimaging techniques like MRI), headache, ARIA-H (micro hemorrhage/superficial siderosis) and fall, according to the Alzheimer's Association.

"The most concerning side effects are swelling of the brain and small hemorrhages," notes Dr. Baumel. "If you stop the medication, those problems typically resolved, and the patients were able to continue the medication."

While some researchers and medical experts were concerned that there was not enough data from the trials to warrant an approval by the FDA, Dr. Baumel says that many people were concerned that we went too long with no treatment.

"At least now we can affect the natural history of the disease," he says. "The historical basis for approving a medication like this comes from the world of cancer therapy where a change in the biology of the tumor is an effect that is interpreted as being good for the patient. Likewise reducing the amount of amyloid in the brain is thought to be good for the patient."

Approval of Aducanumab is a milestone in the treatment of Alzheimer's.

"This drug and the recent news about it increase the amount of the awareness of the disease and gets people talking about it," adds Dr. Baumel. "Overall people with Alzheimer's are suffering but now should be happy that there may be another therapy that could perhaps help them."

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