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FDA CONDITIONALLY APPROVES CONTROVERSIAL ALZHEIMER'S DRUG

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The U.S.'s pharma regulator, the Food and Drug Administration (FDA), made a much anticipated ruling on Monday, in conditionally approving the use of an Alzheimer's drug, called aducanumab, the first such approval since 2003. The drug, which goes by the brand name Aduhelm, has been granted 'accelerated approval', meaning it will need to verify expected clinical benefits in a new trial.

The drug's approval had become controversial, with growing pressure from those impacted by the debilitating degenerative brain disease on one hand and opposition from many in the scientific community who were not convinced that the drug had demonstrated efficacy in trials, on the other. The FDA's conditional approval on Monday took account of this.

On Monday, Patrizia Cavazzoni, director of the FDA's Center for Drug Evaluation and Research, wrote on the organisation's website that "the data included in the applicant's submission were highly complex and left residual uncertainties regarding clinical benefit."

Aducanumab is based on the amyloid hypothesis of the disease — that plaques made of beta amyloid peptide (a type of protein) form in the patients brain leading to cognitive decline and problems with thinking. The drug supposedly binds to beta amyloid molecules and removes them. The drug, a monoclonal antibody, is given monthly via injection to patients who suffer from early stages of Alzheimer's.

'No strong evidence'

The drug, developed by Biogen, a Cambridge (Massachusetts)-based company and Eisai Co., a Japanese company, was pulled out of two trials in 2019 after it was thought not to be working. In October of last year, Biogen said a high dose of the drug slightly slowed cognitive decline.

A panel of experts — not part of the FDA — had ruled last November that the drug did not show "strong evidence" of working. Their decision was non-binding on the FDA. Other scientists and a think tank had said safety concerns around the drug did not outweigh any possible benefits, the *New York Times* reported.

"The late-stage development program for Aduhelm consisted of two phase 3 clinical trials. One study met the primary endpoint, showing reduction in clinical decline. The second trial did not meet the primary endpoint. In all studies in which it was evaluated, however, Aduhelm consistently and very convincingly reduced the level of amyloid plaques in the brain in a dose- and time-dependent fashion. It is expected that the reduction in amyloid plaque will result in a reduction in clinical decline," Ms. Cavazzoni wrote on Monday.

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