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Biogen lays out awaited Alzheimer's drug data in obscure journal

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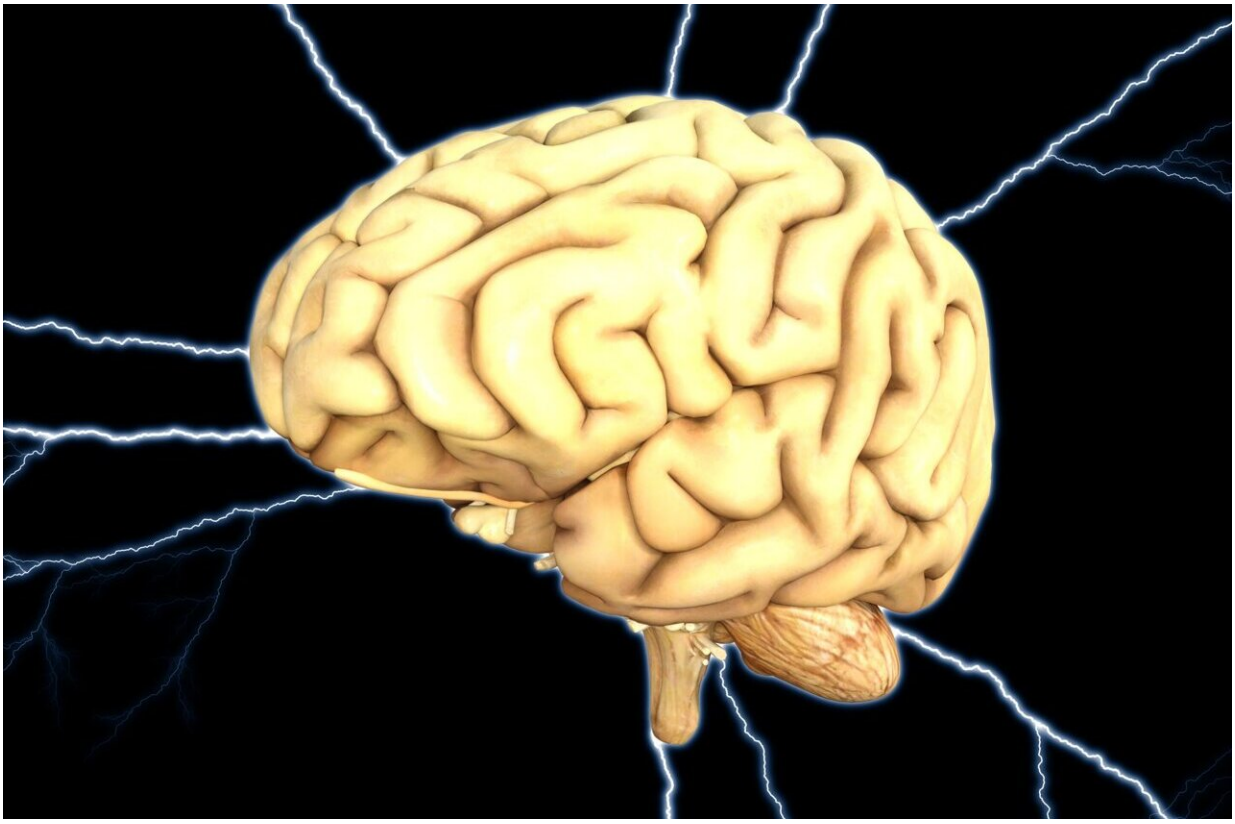

Credit: Pixabay/Pete Linforth.

Biogen Inc. on Wednesday published the full efficacy results from two late-stage studies of its Alzheimer's disease drug Aduhelm in a lesser-known medical journal, nine months after U.S. regulators cleared the

treatment.

Cambridge, Massachusetts-based Biogen had been under pressure to divulge the full details from the trials, which ultimately produced conflicting results after being halted early. One study suggested that the treatment, which removes a plaque called amyloid from the brain, could slow the progression of Alzheimer's. The other did not. The mixed results led to intense debate about whether the drug would provide patients with much benefit.

The results published on Wednesday didn't reveal any new information that is expected to substantially alter the controversy around the drug. The company also said on Wednesday that an extension study showed that after 2 1/2 years of treatment, patients continued to see a decline in key measures of disease pathology.

Biogen still must carry out another trial as a condition of the drug's approval.

Big trials of high-profile new drugs often are published in marquee journals such as the *New England Journal of Medicine* or *Journal of the American Medical Association*. By contrast, the Biogen phase 3 studies were published in the *Journal of Prevention of Alzheimer's Disease*, a relatively lower-profile outlet.

The journal's impact factor, a measure of how frequently articles in a particular publication have been cited in other medical literature, is much lower than names such as the New England Journal, Robert W. Baird & Co analyst Brian Skorney said Wednesday on Twitter.

The publication comes nearly three full years after Biogen first halted the two phase 3 studies, saying the studies suggested the drug was unlikely to work. It later reversed course and concluded that the drug

was effective in one of the two trials, and applied for approval from the Food and Drug Administration.

The contradictory finding, compounded by fact the trials were stopped prematurely, has divided Alzheimer's researchers over how to interpret the results ever since. Publishing the late-stage trials in their entirety could help clear up some of the controversy. However, the company may also come under scrutiny for publishing the results in a lesser-known journal.

Shares of Biogen were up 2% at $201.26 at 2:03 p.m. on Wednesday in New York. The shares have lost roughly half their value since reaching a high of $414.71 on June 10.

The FDA last year granted Aduhelm an accelerated approval, which lets a medicine come to market on the condition that more testing will be conducted. The agency's decision was at odds with the advice from its independent advisers, causing several members of the outside body to resign in protest.

Insurers have been reluctant to pay for Aduhelm without more evidence it slows the progression of the memory-wasting disease. The Centers for Medicare and Medicaid Services has proposed covering the drug for only people enrolled in clinical trials after its review found that while the drug may help patients, it could also cause harm. The agency is expected to issue its final coverage decision next month.

Earlier this week, Biogen said it would take on sole responsibility for turning around Aduhelm, in a revised agreement with its partner Eisai Co. Under the new arrangement, Biogen will pay Eisai a royalty on Aduhelm sales and assume costs of marketing the drug and performing additional testing starting next year.