Reversal of fortune for ‘failed’ Alzheimer’s drug? Biogen now seeking FDA approval, based on new test data

An experimental treatment for Alzheimer’s disease is headed to the Food and Drug Administration for approval—despite the fact that it flunked a “futility analysis” and was abandoned by its maker just months ago.

In March, biotech company Biogen halted two Phase III clinical trials of the antibody drug aducanumab after the analysis of preliminary data suggested it was destined for failure. …

But that March decision was based on data collected only through December 2018. Additional data from those intervening months kept rolling in—and it told a different story, according to Biogen.

Those who received higher doses of aducanumab “experienced significant benefits on measures of cognition and function such as memory, orientation, and language,” the company reported. …

Biogen said it expects to submit the drug for FDA approval in early 2020.

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Biogen says its reversal of fortune came down to more data on patients who were given high doses of aducanumab. That data came from two separate trials, dubbed EMERGE (which enrolled 1,638 patients) and ENGAGE (which included 1,647 patients). Both were Phase III multicenter, randomized, double-blind, placebo-controlled, parallel-group studies testing the safety and efficacy of 18-month regimens of aducanumab at two different doses.

Read full, original post: Alzheimer’s drug that failed early tests now dubbed effective, heads to FDA