## Investigational Alzheimer's drug shows promise

An investigational Alzheimer's drug significantly slowed patients' cognitive decline in a large clinical trial, unexpected and unprecedented results that could move the treatment's makers to roll the dice on an early approval.

In the study, the highest-tested dose of a drug from Biogen and Eisai was markedly better than placebo at delaying the memory-destroying effects of Alzheimer's. After 18 months, patients who got the drug, called BAN2401, performed 30 percent better on a cognitive test than those getting placebo.

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But there are caveats. Four doses of BAN2401 didn't outperform placebo [in the Phase 2 trial], and the high dose was tested on just 161 patients. Furthermore, the metric Biogen and Eisai used to measure mental acuity is a homegrown composite that has never before been used to win Food and Drug Administration approval.

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Biogen and Eisai have not said whether they will take up a larger study to tease out BAN2401's benefits or go straight to the FDA with the Phase 2 results.

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It's unclear whether the FDA will lower the traditionally high bar set for Alzheimer's therapies, which have in the past needed two Phase 3 trials to merit approval.

Read full, original post: Experimental Alzheimer's drug significantly slowed patients' cognitive decline, buoying hopes for treatment (Behind paywall)