

## Positive results from Alzheimer's drug in Phase 1 clinical trial extension

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The pharmaceutical company Biogen has today announced the results of an extended phase 1b clinical trial of the potential Alzheimer's disease drug, aducanumab. Results from the extended early stage trial, were announced today at Clinical Trials in Alzheimer's Disease (CTAD) conference in Boston.

Aducanumab is an antibody that targets amyloid, a protein that builds up in the brains of people with Alzheimer's disease. Several drugs have been designed to target this process, but none has yet succeeded in improving outcomes for people living with Alzheimer's disease.

Last year, researchers published results from a 54-week trial in which 165 people with early Alzheimer's disease received monthly injections of aducanumab, at doses of either 1, 3, 6 or 10 mg/kg, or a placebo injection of saline solution. The findings indicated that people who received the drug had lower levels of amyloid in the brain on brain scans and a slower decline in memory and thinking skills. Those who received the highest, 10mg/kg dose, showed the strongest signs of a benefit.

The researchers have continued to work with this group of participants, and now have results from patients who have been taking the drug for up to 36 months. The findings presented at the conference today point to a continued benefit over the extension period, with further reductions in amyloid levels, and slower decline in memory and thinking skills in people who took higher doses of the drug. In one test of memory and thinking skills, participants who received 10mg/kg throughout the 3



years of the study experienced around half the decline as those who received a placebo followed by a low dose.

The trial extension involved patients who were receiving a <u>placebo</u> <u>treatment</u> throughout the original trial and who switched to receive aducanumab for the 2-year extension period. These results show that people who had been treated with the drug initially as part of the trial, continued to have slower decline than those moved over to the drug from placebo later on. This is a technique used in clinical trials to explore whether a drug may be slowing a disease rather than just improving the symptoms.

In the original trial, around a quarter of participants who received the drug experienced a condition called ARIA, which is characterised by leakage of fluid from the blood into the brain. The researchers report that there were no new cases of ARIA in people who continued on the same dose of aducanumab in the extension, but that they saw a similar proportion of cases in people who transferred from the placebo treatment.

Aducanumab is currently being tested further in phase III <u>clinical trials</u>. These trials are currently recruiting people in the UK who have a confirmed diagnosis of mild cognitive impairment (MCI) or mild Alzheimer's disease. Volunteers need to be willing to undergo testing for risk genes and have multiple assessments including brain scans and blood tests. Anyone interested can sign up to Join Dementia Research at <u>www.joindementiaresearch.nihr.ac.uk</u> or by calling Alzheimer's Research UK on 0300 111 5111.

Dr Carol Routledge, Director of Research at Alzheimer's Research UK, said:

"It has been over 15 years since the last Alzheimer's treatment came to



market and the treatments that are currently available only offer modest, temporary benefits. The results of this small extension study add to previous promising signs from the trial that aducanumab could act on underlying <u>disease</u> processes in Alzheimer's.

"Not only did aducanumab help to clear the amyloid protein from the brain, but the fact that the benefits of the drug were greater for those people who took the <u>drug</u> over 36 months compared to 24 months is an encouraging sign. Other drugs that have shown promise at this stage of testing have not gone on to succeed in later stage trials, so we will only know what the future holds for aducanumab when we see results from the larger ongoing phase III <u>trials</u>.

"Alzheimer's Research UK is committed to bringing about life-changing treatments for dementia but this will only be possible if enough people volunteer to take part in research. Anyone interested in volunteering for dementia research, including the current phase III trial of aducanumab, can sign up to Join Dementia Research at www.joindementiaresearch.nihr.ac.uk or by calling Alzheimer's Research UK on 0300 111 5 111."

## Provided by Alzheimer's Research UK

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