Small patient pool in Alzheimer's drug trial casts shadow on positive results

Facing pressing questions about its latest clinical trial in Alzheimer's disease, Biogen may have sowed further doubt on the future of an investigational treatment on [October 25].

At a medical conference in Spain, Biogen and partner Eisai presented data on the drug, BAN2401, meant to clear up concerns that its earlier observed benefits were a mirage. But the explanation revealed that <u>BAN2401's glimmer of promise</u> is based on results from a small subset of patients in an otherwise large trial, which could be difficult to replicate in later studies.

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Eisai argued in favor of the drug, presenting new analysis showing that patients on placebo saw their Alzheimer's worsen at similar rates regardless of whether they had the genetic mutation [which worsens Alzheimer's], called APOE4. Digging into the data from the high-dose group, Eisai said patients with APOE4 actually did better on BAN2401 than those without, compared to placebo.

"Therefore we believe that the treatment effect was not due to an imbalance in subject allocation, but that it may have actually underestimated the overall BAN2401 effect," said Chad Swanson, Eisai's director of clinical research in neuroscience.

But that conclusion is based on an analysis of only 10 patients with APOE4 mutations who got the high dose of BAN2401, and their results are compared against 113 subjects on placebo.

Read full, original post: Biogen's 'positive' Alzheimer's trial has a problem with small numbers