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J&J, Pfizer halt phase III trial of Alzheimer's drug

August 7, 2012 | News | By BioSpectrum Bureau

J&J, Pfizer halts Ph 3 Bapineuzumab clinical trial for Alzheimer's Disease



Singapore: Johnson & Johnson (J&J) discontinued phase III clinical development of bapineuzumab intravenous (IV) that is used in the treatment of mild-to-moderate Alzheimer's disease.

Janssen Alzheimer Immunotherapy (Janssen AI), a subsidiary of Johnson & Johnson, is a partner with Pfizer in the Alzheimer's Immunotherapy Program (AIP). The Joint Steering Committee for the AIP decided to discontinue the development of bapineuzumab IV in mild-to-moderate Alzheimer's disease as the co-primary clinical endpoints were not being met in the Janssen AI-led Studies 301 and 302.

Dr Husseini K Manji, head, Neuroscience, global therapeutic area, R&D, Janssen, said that, "While we are disappointed in the results of the two bapineuzumab IV studies, particularly in light of the urgent need for new advancements in Alzheimer's disease, we believe that targeting and clearing beta amyloid remains a promising path to potential clinical benefits for people suffering from this disease."

He further said that, "Janssen remains strongly committed to tackling the enormous unmet medical needs in Alzheimer's disease. We believe the trial results will provide a rich data set that will advance our understanding of this complex disease and inform future research in this field. Studies with other compounds in earlier stages of development in the AIP portfolio are continuing and future development strategies will be discussed jointly by the alliance partners."

The company expects to record an after-tax, non-cash special item related to in-process research and development consisting of a net charge to earnings of between $300 and $400 million in the third quarter of 2012 related to the discontinuation of the phase III clinical development of bapineuzumab IV in mild-to-moderate Alzheimer's disease.

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Four placebo-controlled phase III studies comprised the bapineuzumab clinical development program. Janssen led the two completed 18-month, phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group, efficacy and safety studies of patients who are ApoE4 carriers (Study 302) and ApoE4 non-carriers (Study 301).

The two co-primary clinical endpoints changed in the Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog), which is a validated measure of cognition, and also in the the Disability Assessment for Dementia (DAD), a validated instrument to measure function.