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Pfizer Announces Co-Primary Clinical Endpoints Not Met In Second Phase 3 Bapineuzumab Study In Mild-To-Moderate Alzheimer's Disease Patients Who Do Not Carry The Apoe4 Genotype

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Pfizer and Janssen Alzheimer Immunotherapy Discontinue Bapineuzumab IV Phase 3 Program

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(BUSINESS WIRE)--**Pfizer Inc**. **(NYSE: PFE)** announced today that the co-primary clinical endpoints, change in cognitive and functional performance compared to placebo, were not met in the Janssen Alzheimer Immunotherapy R&D LLC (Janssen AI)-led Phase 3 trial of intravenous (IV) bapineuzumab in patients with mild-to-moderate Alzheimer's disease who do not carry the ApoE4 (apolipoprotein E epsilon 4) genotype (Study 301). Pfizer and Janssen AI are partners in the Alzheimer's Immunotherapy Program (AIP).

Based on the topline results of this study, together with the topline results of a Janssen AI-led Phase 3 study in patients who carry the ApoE4 genotype (Study 302)announced on July 23rd, the Janssen AI and Pfizer Joint Steering Committee for the AIP has decided to discontinue all other bapineuzumab IV studies in patients with mild-to-moderate Alzheimer's disease. This includes not only the Pfizer-led, Phase 3 studies (Study 3000 and Study 3001), but also all follow-on extension studies in patients with mild-to-moderate Alzheimer's disease receiving bapineuzumab IV. All patients in the discontinued studies will have a follow-up evaluation and the Alliance will conduct final data analyses.

These clinical findings and the decision to discontinue the bapineuzumab IV program in patients with mild-to-moderate Alzheimer's disease have been shared with regulatory authorities and study investigators.

"We are obviously very disappointed in the outcomes of this trial. We are also saddened by the lost opportunity to provide a meaningful advance for patients afflicted with mild-to-moderate Alzheimer's disease and their caregivers," said Steven J. Romano, M.D., senior vice president, head, Medicines Development Group, Global Primary Care Business Unit, Pfizer Inc. "Yet these data, and the subgroup and biomarker analyses underway, will further inform our understanding of this complex disease and advance research in this field."

No new safety concerns were identified in Study 301. The most commonly observed serious adverse events which occurred in bapineuzumab-treated patients more commonly than in placebo-treated patients, and with an incidence of at least 1 percent in the combined 0.5 mg/kg and 1.0 mg/kg group, were pneumonia, ARIA-E (amyloid-related imaging abnormalities-edema or effusion), syncope, hip fracture and convulsion.

Data from both Study 302 and Study 301 have been accepted as a late-breaker and will be presented in September at the European Federation of Neurological Societies (EFNS) meeting in Stockholm.

About the Bapineuzumab IV Phase 3 Studies

Four placebo-controlled Phase 3 studies comprised the bapineuzumab IV clinical development program. Janssen AI led the two completed 18-month, Phase 3, 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 were change in the Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog), a validated measure of cognition, and the Disability Assessment for Dementia (DAD), a validated instrument to measure function. Study 302 included approximately 1,100 patients who carry the ApoE4 genotype. Additionally, Study 301 reported here included approximately 1,300 patients who do not carry the ApoE4 genotype.

In addition to the Janssen AI-led studies, Pfizer led two primarily ex-North American 18-month, Phase 3, multicenter, randomized, double-blind, placebo-controlled, parallel-group, efficacy and safety studies of patients with mild-to-moderate Alzheimer’s disease who are ApoE4 non-carriers (Study 3000) and carriers (Study 3001).

About Bapineuzumab IV

Bapineuzumab IV, an investigational therapy studied for the treatment of mild-to-moderate Alzheimer’s disease, is an antibody that targets beta-amyloid (A?), a protein that can exert toxic effects in the brain and is believed to play a central role in the pathology of Alzheimer’s disease.

About Alzheimer’s disease

Alzheimer’s disease, the most common form of dementia, is a degenerative brain disease that is not a normal part of aging. Currently there is neither a cure nor a treatment that delays the course of Alzheimer’s disease, which gradually destroys a person’s cognitive and functional abilities, including memory and the ability to perform activities of daily living, such as bathing and eating. Alzheimer’s disease is the sixth leading cause of death in the United States, estimated to affect more than five million people. It is estimated that there were 35.6 million people with dementia, including Alzheimer’s disease, worldwide in 2010. This number is projected to nearly double every 20 years, increasing to 65.7 million in 2030 and 115.4 million in 2050 worldwide. Furthermore, the total worldwide costs of dementia, including Alzheimer's disease, were estimated around one percent of global gross domestic product (GDP) in 2010, at more than US$600 billion. This includes costs attributed to informal unpaid care, community or residential-based care and treatment.

About the Alzheimer’s Immunotherapy Program (AIP)

The Alzheimer's Immunotherapy Program (AIP) of Janssen Alzheimer Immunotherapy and Pfizer Inc. is an equal collaboration committed to researching and developing selective products for the treatment and/or prevention of neurodegenerative conditions, including Alzheimer’s disease.

We believe that it may be possible to reduce the burden of disease through early intervention in the illness. The AIP is dedicated to delivering comprehensive and integrated solutions that help address the needs of people impacted by Alzheimer’s disease.

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At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us.

DISCLOSURE NOTICE: The information contained in this release is as of August 6, 2012. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a product candidate, bapineuzumab, that involves substantial risks and uncertainties including, among other things, the uncertainties inherent in research and development. A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and in its reports on Form 10-Q and Form 8-K.

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