Pfizer Announces Topline Results Of First Of Four Studies In Bapineuzumab Phase 3 Program

Monday, July 23, 2012 - 07:31am

Co-Primary Clinical Endpoints Not Met in Study of Patients with Alzheimer’s Disease Who Carry The ApoE4 Genotype

"We recognize that Alzheimer’s disease is very complex, but Pfizer, along with our partner Janssen AI, remains committed to advancing the science of Alzheimer’s disease, with the ultimate goal of delivering innovative and meaningful new treatment options to patients."

(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 carry the ApoE4 (apolipoprotein E epsilon 4) genotype (Study 302). Pfizer and Janssen AI are partners in the Alzheimer’s Immunotherapy Program (AIP).

These clinical findings have been shared with regulatory authorities and study investigators so that participants in the ongoing clinical program can be informed. Because in this study clinical efficacy was not demonstrated in ApoE4 carriers, the Janssen AI and Pfizer Joint Steering Committee for the AIP has decided that participants from this study who enrolled in a follow-on extension study will no longer receive doses of bapineuzumab. However, these patients will have a follow-up evaluation.

Based on a comprehensive review of the data by the independent safety monitoring committee, all other ongoing Janssen AI and Pfizer bapineuzumab studies are continuing

as planned and without modifications.

Study 302 is the first of four placebo-controlled Phase 3 studies to complete in the comprehensive development program of bapineuzumab IV. Janssen AI is leading two Phase 3 studies of patients who are ApoE4 carriers (Study 302) and non-carriers (Study 301) at sites primarily in North America. Pfizer is conducting two Phase 3 studies of patients who are ApoE4 carriers (Study 3001) and non-carriers (Study 3000) at sites primarily outside of North America.

The Alliance will expedite the completion of an interim analysis for the on-going, Pfizer-conducted Phase 3 study of ApoE4 carriers (Study 3001) based on the results of Study 302.

The topline results from Study 301 in patients with mild-to-moderate Alzheimer's disease who do not carry the ApoE4 genotype are expected to be announced later this summer.

"While we are disappointed in the topline results of Study 302, a more complete understanding of bapineuzumab and its potential utility in mild-to-moderate Alzheimer's disease will be gained following the availability of additional data, including data from the soon-to-be available non-carrier Study 301," said Steven J. Romano, M.D., senior vice president, head, Medicines Development Group, Global Primary Care Business Unit, Pfizer Inc. "We recognize that Alzheimer's disease is very complex, but Pfizer, along with our partner Janssen AI, remains committed to advancing the science of Alzheimer's disease, with the ultimate goal of delivering innovative and meaningful new treatment options to patients."

Data from both the ApoE4 carrier (Study 302) and non-carrier (Study 301) studies have been accepted as a late-breaker and will be presented in September at the European Federation of Neurological Societies meeting in Stockholm.

The presence of the ApoE epsilon 4 genotype is a genetic risk factor for Alzheimer's disease and is associated with increased beta-amyloid plaques in the brains of patients with the disease. Topline results of Study 302 indicate that among patients treated with bapineuzumab IV the most commonly observed serious adverse events which occurred more commonly than placebo and with an incidence of at least 1 percent were ARIA-E and dehydration. ARIA-E (amyloid-related imaging abnormalities-edema or effusion) refers to changes in the brain that may be due to fluid (water and protein) leaking from blood vessels, which can be detected using magnetic resonance imaging (MRI) of the brain.

About the Bapineuzumab IV Phase 3 Studies

There are four placebo-controlled Phase 3 studies in the bapineuzumab clinical development program. Janssen AI is leading two 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 are 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 and Study 301 includes approximately 1,300 patients who do not carry the ApoE4 genotype.

In addition to the Janssen AI-led studies, Pfizer is conducting two primarily ex-North America 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 being studied for the treatment of mild-to-moderate Alzheimer’s disease, is an antibody that targets beta-amyloid (Aβ), 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

The Alzheimer's Immunotherapy Program 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 is 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.

Pfizer Inc.: Working together for a healthier world™

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 July 23, 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, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial completion dates and regulatory submission dates; whether and when any drug applications may be filed in any jurisdictions for bapineuzumab; whether and when any such applications may be approved by regulatory authorities as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

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.

Pfizer Inc. Media: MacKay Jimeson, 212-733-2324MacKay.Jimeson@pfizer.com or Investor: Suzanne Harnett, 212-733-8009Suzanne.Harnett@pfizer.com