New Research Presented At Alzheimer’s Association International Conference On Alzheimer's Disease Indicates Alzheimer’s Disease May Lead To Increased Comorbid Conditions And Economic Burden

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE), together with its collaborator on the Alzheimer’s Immunotherapy Program, Janssen Alzheimer Immunotherapy, presented new research this week at the Alzheimer’s Association International Conference on Alzheimer's Disease 2010 (ICAD 2010) from two podium and four poster presentations. This research indicates there may be potential for an increased risk of comorbid conditions, such as seizures, stroke and type 2 diabetes, with Alzheimer’s disease (AD). These studies also provide new findings about the burden of care and costs associated with AD for patients and their caregivers.

“These findings underscore the importance of advancing research about the growing burden and costs of AD. We need to increase our understanding of the needs of patients and caregivers, as well as the economic costs of this disease,” said Ronald Black, M.D., assistant vice president, Clinical R&D, on behalf of the Alzheimer’s Immunotherapy Program. “The Alzheimer's Immunotherapy Program is committed to advancing such

research as well as working to develop new therapies to help fight this devastating disease.”

About the Oral and Poster Presentations

Oral #O2-06-04: Alzheimer's Disease is Associated with Increased Incidence of Seizures Among Patients in the United Kingdom, 1988-2009 (Baker N, et al.)

This retrospective cohort study was designed to estimate the incidence of seizures among AD patients and non-AD patients. The study was conducted using anonymized electronic medical records of 14,838 AD patients aged 50 years or older and 14,838 sex-age-matched non-AD patients from nearly 400 primary practices in the United Kingdom. AD patients were followed for an average of 2.3 years and non-AD patients were followed for 3.4 years.

The findings showed that people with AD have seizures at an annual rate of nearly 1 percent, which is slightly more than 6-fold higher (95 percent CI, 4.9-8.4) than persons of similar age and gender without AD. The study also showed the risk for seizure among those with AD was highest at younger ages and decreased with increasing age. The incident rate of seizures among non-AD patients increased slightly with age. In this study, no safety data related to any particular product were collected. One of the limitations of this study was the inability to assess AD severity. In addition, events recorded in the electronic medical record were not confirmed.

Poster #P3-078: The Incidence of Stroke is Increased Among Patients with Alzheimer’s Disease in the United Kingdom, 1988-2009 (Baker N, et al.)

This retrospective cohort study aimed to estimate the rate of stroke among AD patients and non-AD patients. The study was conducted using anonymized electronic medical records of 13,694 AD patients aged 50 years or older and 13,694 sex-age-matched non-AD patients from nearly 400 United Kingdom primary practices.

The patients with AD were followed for an average of 2.3 years and the non-AD patients were followed for an average of 3.4 years.

The study found that the incidence of stroke in patients diagnosed with AD is 1.6 (95 percent CI, 1.4-1.8) times greater than that of non-AD patients. The increased incidence rate of stroke comparing AD patients to non-AD patients was seen in all age groups. Patients with AD and their caregivers should be educated on the signs and symptoms of a stroke. In this study, no safety data related to any particular product were collected. One

of the limitations of this study was the inability to assess AD severity. In addition, events recorded in the electronic medical record were not confirmed.

Poster #P3-087: Central Nervous System (CNS) Comorbidities and Concomitant Drug Use in a Medicaid AD Population (Mucha L, et al.)

This is the first multi-state study to use Medicaid records from 2000-2008 to examine the differences in CNS comorbidities and concomitant drug use and costs. A total of 13,927 AD patients were matched to non-AD patients by several key factors, including age, gender and Medicare eligibility status, among others. AD patients qualified for inclusion into the study after their first instance of AD-related dementia and a second AD claim or a prescription for an AD treatment. The primary outcomes measures were medical and pharmacy utilization and costs during the first year.

The study found that a significantly ($P<0.0001$) higher number of AD patients were diagnosed with any CNS condition compared to the control group, including psychosis (57 percent vs. 4 percent), depression (15 percent vs. 6 percent) and major depression (7 percent vs. 3 percent). Atypical antipsychotics were the most commonly utilized drug class by AD patients and represented the highest drug expenditure category for AD patients. This study showed that, due to their prevalence, CNS comorbidities and treatment among AD patients represent a substantial cost to the healthcare system.

No safety data were collected. Study limitations included the unavailability of AD severity information and the AD inclusion criteria, which may have resulted in excluding some AD patients. Also given changes to the Medicare D database, any patient over age 65 included in the study must have met the study criteria prior to 2006.

Poster #P3-061: The Contribution of Type 2 Diabetes to the Burden of Alzheimer’s Disease (Mucha L, et al.)

Many patients with AD also suffer from type 2 diabetes, but it’s unclear how type 2 diabetes may impact the burden of AD. This new, large, multi-state Medicare claims database study examined the cost and utilization differences between AD patients with and without type 2 diabetes. AD patients were identified from a claims database by the first instance of AD-related dementia and a second AD claim or a prescription for an AD treatment. The presence of type 2 diabetes was then established based on medical and/or pharmacy claims for insulin or oral hypoglycemics. The primary outcomes measures were health care cost and utilization during the first year.

The study showed that AD patients with type 2 diabetes have significantly higher rates of other chronic conditions, greater healthcare service use and higher healthcare costs than AD patients without type 2 diabetes. Specifically, AD patients with type 2 diabetes had significantly higher rates (approximately 1.5-fold higher) of hypertension, hyperlipidemia and decubitus ulcer than AD patients without type 2 diabetes. AD patients with type 2 diabetes also utilized more health care services, such as ambulatory, inpatient emergency room, and skilled nursing facilities ($p<0.001$ for all). In addition, in this study the average annualized total healthcare costs for AD patients with type 2 diabetes were 33 percent higher than those of AD patients without type 2 diabetes.

No safety data were collected. Study limitations included the unavailability of AD severity information and the AD inclusion criteria, which may have resulted in excluding some AD patients. Finally, while the non-type 2 diabetes cohort was not matched to the type 2 diabetes cohort, the regression model controlled for any differences in various demographic characteristics and comorbidities.

Oral #O3-04-01: Utilization and Expenditures Associated with Long Term Care in Medicaid Alzheimer’s Disease Patients Compared to a Matched Non-AD Medicaid Cohort (Mucha L, et al.)

A new, large, multi-state Medicaid claims database study aimed to analyze the differences in long term care (LTC) utilization and expenditures among Medicaid patients with and without AD. The study compares records of AD Medicaid patients (13,927 AD participants) matched with non-AD Medicaid patients.

Patients with AD aged 50 years and older were retrospectively identified after their first instance of AD-related dementia and a second AD claim or a prescription for an AD treatment. In this study, LTC was defined as non-home chronic care including, nursing homes and skilled nursing facilities, among others. Resource utilization and reimbursement amounts for LTC occurring in the first year were measured.

In this study, AD patients were more likely to have an LTC claim; higher total expenditures; and a higher percent of their expenditures represented by LTC claims. This study also showed that LTC expenditures for AD patients were 61 percent higher than those of the matched cohort. This study highlights the importance of institutional care costs for AD patients to the Medicaid programs, as well as the potential value of any therapies that might help delay or avoid need for institutionalization. A limitation of this research is that claims data are collected for payment and not for research; and thus are subject to possible coding errors. However, the impact of potential coding errors was

minimized because patients were required to have two or more diagnosis codes for AD on separate service dates or an AD diagnosis code in conjunction with at least one claim for medication used to treat AD.

Poster #P3-014: Quantifying Caregiver Out-Of-Pocket Expenses and Time Spent Caregiving (Racketa J, et al.)

Since caregiver out of pocket expenditures (OOPE) have not been well documented, this comprehensive Internet-based survey aimed to estimate the cost per AD patient within the community-dwelling (CD) and long-term care (LTC) setting by evaluating caregiver time and OOPE. Data from 987 caregivers were included in this analysis, of which, 901 provided care for CD patients and 86 provided care for patients in LTC.

Caregivers were asked to report their monthly AD-related OOPE as well as hours spent providing care each week. OOPE included AD patient medical costs; supportive services such as day care, transportation, and home health aids; caregiving support services; nursing home care; home modifications; and legal fees.

This study highlights that the financial burden placed on U.S. caregivers of AD patients is significant in both CD and LTC; however, in this study, the average monthly OOPE for caregivers is higher for LTC vs. CD setting at $1,039 ($202 SE) and $374 ($53 SE), respectively. This study also found that caregivers spent an average of 68.2 (1.8 SE) hours per week providing care to CD patients compared to 24.8 (3.4 SE) for LTC patients. As AD progresses and requires LTC, considerable costs are passed on to the caregiver. Study limitations included the fact that OOPE were self-reported by caregivers. In addition, patient OOPE were estimated by the caregiver, but not reported in this study.

Editors Note: The Alzheimer's Immunotherapy Program of Janssen Alzheimer Immunotherapy and Pfizer Inc. also presented the following abstracts at ICAD:

Oral #O3-05-01: Immunotherapy with Bapineuzumab Lowers CSF Tau Protein Levels in Patients With Alzheimer's Disease (Blennow K, et al.)

Poster #P3-067: A Systematic Literature Review and Meta-analysis of Apolipoprotein E ε4 Prevalence in Alzheimer’s Disease Patients (Crean S, et al.)

Poster #P2-187: Longitudinal Changes in Functional Disability in Alzheimer’s Disease Patients (Arrighi M, et al.)

About Alzheimer’s Disease

Alzheimer’s disease (AD), the most common form of dementia, is a fatal, degenerative brain disease that gradually destroys a person’s memory and ability to learn, reason, make judgments, communicate and carry out daily activities, such as bathing and eating. As AD progresses, individuals may also experience changes in personality and behavior, such as anxiety, suspiciousness or agitation, delusions or hallucinations.

Statistics on the prevalence and impact of AD vary depending on how the disease is defined and methods used in gathering data. Published reports estimate the worldwide prevalence of AD to be 26.6 million people. This number is projected to quadruple to 106.2 million people in 2050 with 1 in 85 persons living with the disease. In the United States alone, recent estimates indicate as many as 2.4 million to 5.3 million Americans have AD.

AD is among the most costly diseases worldwide. The annual cost of dementia, including AD, has been estimated at $315 billion.

In the United States, the indirect and direct costs of caring for people with AD are estimated to be more than $100 billion a year. An aging global population will result in an increased burden on people living with AD, caregivers and public health systems worldwide.

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 AD.

We believe that it is possible to reduce the burden of disease through early intervention in the illness. The Alliance is dedicated to delivering comprehensive and integrated solutions that help address the needs of people impacted by AD.

The research of the Alliance focuses on the beta amyloid hypothesis. Scientific evidence supports the idea that the accumulation of beta-amyloid may play an important role in the pathophysiology of AD. It is believed that preventing the accumulation and/or promoting the removal of beta-amyloid may have the potential to slow the progression of AD and help preserve function in people with AD. This theory is being tested in clinical trials.

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