FOR IMMEDIATE RELEASE
October 25, 2012

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GLOBAL RESEARCH COMMUNITY PRESENTS NEW FINDINGS AT CTAD 2012 AND SETS PATH FOR AD DRUG DEVELOPMENT

Monte Carlo, Monaco (October 25, 2012) – The 5th International Conference on Clinical Trials for Alzheimer's Disease (CTAD) will provide the stage for a closer examination of the unexpected outcomes of Phase 3 treatment trials with some encouraging findings this year – the first such results in the Alzheimer's field in almost a decade. The 2012 program will also analyze building evidence that can help focus global research dollars and priorities, namely that detecting AD years, even decades, before clinical symptoms appear offers the best opportunity for current and new drugs to work.

Researchers will also discuss important goals in worldwide AD research, including improving early detection and accurate diagnosis methods, harmonization of imaging techniques across patient populations, identifying factors that affect AD progression, and advancement in AD biomarkers. Chairing the conference are Paul Aisen, MD, University of California at San Diego; Jacques Touchon, MD, University of Montpellier; Bruno Vellas, MD, University of Toulouse; and Michael Weiner, MD, University of California at San Francisco.

Since its debut in Montpellier, France in 2008, CTAD has maintained its unique role in AD research as an intimate professional forum for the world's preeminent clinical researchers to share ideas and foster international collaboration toward progress in a disease that threatens the health of all nations and is soon expected to become the single largest health care expense for many. Alzheimer's is a progressive and ultimately fatal neurodegenerative disease that today affects more than 35 million individuals, robbing them of their memory, independence, and ability to think and understand. By 2050, the number of people with AD is expected to exceed 115 million worldwide if nothing is done to slow or prevent the disease.

"The research presented at CTAD and the very nature of the meeting are critical to creating a clear path for global research in Alzheimer's disease," said Michael W. Weiner, MD, Director, Center for Imaging of Neurodegenerative Diseases at the San Francisco Veterans Affairs Medical Center and co-organizer and a spokesman for the conference. "No one country is going to be able to solve Alzheimer's alone, and we are bringing together the best in the field to spur better discoveries faster."

Research materials will be posted under the CTAD press tab as embargoes lift at: http://www.ctad.fr/12-press/press.asp. Highlights of the CTAD 2012 symposia, oral communications, plenary presentations, and poster sessions include the following:

Solanezumab and Bapineuzumab Trials

Further results from the solanezumab Phase 3 studies will be presented. This includes the release of an analysis of pooled data from solanezumab trials examining AD fluid biomarkers and neuroimaging measures. The solanezumab studies demonstrated cognitive benefits, especially in those with mild dementia. These results, as well as new biomarker data from MRI, CSF, and amyloid PET scan studies in the solanezumab trials, will be presented at CTAD in two symposia.

Reporting on all studies is under embargo until the time of presentation. See the full program at www.ctad.fr/.

Safety and Efficacy of Solanezumab in Patients with Mild to Moderate Alzheimer's Disease: Results from Phase 3, *Rachelle S. Doody, MD, PhD, Baylor College of Medicine - Department of Neurology, Houston, Texas, USA will be held October 29th, 4:30 – 4:50 p.m.*

Update in Clinical Trials [solanezumab] is part of Symposium 5 on October 30th, 11:00 a.m.

While the results from the bapineuzumab Phase 3 studies in mild to moderate Alzheimer's disease patients did not show cognitive or functional benefits, encouraging biomarker data demonstrated a stabilization in the amount of amyloid plaque and an effect on neurodegeneration as indicated by a decrease in CSF phospho-tau protein.

Bapineuzumab IV Phase 3 Results will be presented in Symposium 2 on October 29th, 11:15 a.m. Chairman: Philip Scheltens, VU University Medical Center, Alzheimer Center, Amsterdam, the Netherlands; Presenters: Reisa Sperling, Brigham & Women's Hospital, Boston, MA, USA; Stephen Salloway, MD, Butler Hospital, Providence, RI, USA; Nick Fox, UCL, Institute of Neurology, London, United Kingdom.

Preventing AD with a Multi-Domain Intervention

Researchers from the University of Montpellier and University of Toulouse will present imaging and clinical data from the MAPT trial (MultiDomain Alzheimer's Preventive Trial). MAPT represents the first multidomain preventive trial in AD. The goal of MAPT is to assess whether the combination of physical exercise, cognitive exercise, and nutritional supplementation with omega 3 fatty acids is effective in preventing or slowing cognitive and functional decline.

Preliminary results comparing the intervention subjects with controls suggest some improvement at 6 and 12 months in brain metabolism.
These data will be presented in Symposium 7 – October 30th, 4:30 p.m.

Presymptomatic Trials: Are We Ready?

Enthusiasm for testing drugs in the presymptomatic phase of the disease is tempered by two major challenges: how to identify and enrich a study with individuals who are cognitively normal but on track to develop AD, and how to assess the ability of a drug to slow the subtle changes that occur in the earliest stages of the disease. Researchers at the University of California, San Diego examined rates of decline in subjects with mild cognitive impairment (MCI) and in elderly subjects who were cognitively normal.

The researchers found that long natural history studies of AD are needed to understand the biomarker changes that precede dementia, and to pinpoint specifically when the biomarkers of currently clinically normal patients start to change rapidly to help measure clinical efficacy of treatment.
These data will be presented in session OC14 – October 30th, 1:00 p.m.

The same research team has also shown that it may be difficult to distinguish AD from normal aging in the oldest old, since clinical decline and brain atrophy tend to slow with advanced age in individuals with MCI and AD, but speed up in healthy controls. This would indicate that younger cohorts are desirable to detect change, and older people are needed to help confirm how well therapies are tolerated across the age spectrum.
These data will be presented in session OC13 – October 30th, 8:30 a.m.

Standards that Can Help the Global Field Work More Seamlessly

As AD drug development has increasingly become a global enterprise, there has been growing recognition of the need for standardized protocols to diagnose disease and assess and report treatment effects. Groundbreaking

progress has been made by the Alzheimer's Disease Neuroimaging Initiative (ADNI) and its worldwide partners. Building on the success of ADNI, international partnerships have emerged for harmonizing analytical protocols in several areas. Harmonized measurement can facilitate regulatory involvement and approval, and help speed the clinical application of disease-modifying treatments shown to be effective in clinical trials.

Specific efforts that will be featured at CTAD2012 include:

- After four years of work, an international task force has reached consensus on a protocol for measuring brain volume in the hippocampus, an area of the brain associated with memory, which is most affected by neurodegeneration in AD. Once validated, this protocol will enable comparison and comingling of data collected at different sites in clinical trials.
  These data will be presented in session OC8 – Definition of Harmonized Protocol for Hippocampal Segmentation, October 29th, 3:15 p.m.

- A standardized and validated assay has also been developed by Meso Scale Discovery for measuring the levels of two biomarkers in the cerebrospinal fluid CSF that are used to determine if a patient has AD or MCI.
  These data will be presented in session OC18 – Towards Standardization of CSF Biomarkers: A Multi-Site Study Using Validated Assays for Aβ42 and Tau, October 30th, 2:00 p.m.

- Recognizing that different requirements from regulatory agencies around the world can slow the approval of new treatments for AD, representatives from U.S. and European regulatory agencies and non-profit organizations have joined forces to spur global consensus on regulatory requirements and propose a collaborative mechanism.
  These data will be presented in session S1 - Harmonizing Regulatory Requirements to Benefit Future Alzheimer's Disease Patients, October 29th, 8:45 a.m.

- The STARDdem (STAndards of Reporting Diagnostic test accuracy, dementia) initiative has developed draft guidelines for authors and editors to use when reporting the results of clinical trials to ensure accuracy and transparency. These guidelines will be discussed at CTAD, prior to being submitted for publication as a consensus statement.
  These data will be presented in session 6 – Harmonization of Reporting Standards for Studies of Diagnostic Test Accuracy in Dementia: The STARDdem, October 30th, 9:45 a.m.

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About CTAD

Since 2008, CTAD has been a conference organized and planned by Alzheimer's disease (AD) clinical researchers for AD clinical researchers. CTAD embraces the organizing committee mandate to maintain CTAD's unique role in AD research: To provide a substantive, clinical research-oriented conference and an annual opportunity for the world's preeminent clinical researchers to engage in both formal and informal exchanges of views. CTAD's ongoing commitment to providing a relatively intimate forum has resulted in the conference's reputation of facilitating and fostering international collaboration in AD clinical research matters. More information is available at www.ctad.fr/.

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