ACT-AD
Accelerate Cure/Treatments for Alzheimer's Disease

ACT-AD and FDA Focus on Evaluating Clinical Effectiveness in Early Alzheimer's Disease

-- Scientists and FDA discuss options to guide research and drug availability --

Rockville, MD, July 21, 2009 – The ACT-AD (Accelerate Cure/Treatments for Alzheimer's Disease) Coalition today hosted the second in a series of defining meetings with a senior representative from the US. Food and Drug Administration (FDA), leading scientists, drug developers and AD advocates to address critical issues affecting the review and approval of new therapies for Alzheimer's disease (AD). Participants focused on the FDA's current standards for defining clinical meaningfulness, especially in Mild Cognitive Impairment/Early Alzheimer's Disease (MCI/EAD); explored potential alternatives to global or functional assessments in these patients; reviewed the need for better trial design; and considered learnings on MCI/EAD from other regulatory agencies.

The meeting was coordinated by ACT-AD, a coalition of national organizations seeking to accelerate development of potential cures and treatments for AD, and co-hosted by The Alzheimer's Association and Leaders Engaged in Alzheimer's Disease (LEAD). "Over the past three years, ACT-AD's member organizations and our partners have coordinated a series of historic meetings with the FDA that have brought expert consensus on key Alzheimer's issues to the Agency and built a momentum of collaboration that today resulted in concrete progress toward a workable definition of clinical effectiveness in early stages of the disease. And just in time," said Daniel Perry, chair of the ACT-AD Coalition. "Literally each day brings greater hope for breakthroughs, but it also brings greater urgency as we continue to fight this disease individually and as a nation. So we will work together to build on today's discussion and ready a workable definition of clinical meaningfulness that meets the greatest healthcare challenge of our time."

Meeting participants included:

- **Dr. Russell Katz**, FDA -- Director of the Division of Neurology Products
- **Dr. Jeffrey Cummings**, University of California, Los Angeles -- Director of the Alzheimer's Disease Center
- **Dr. Howard Fillit**, Alzheimer's Drug Discovery Foundation -- Executive Director
- **Dr. Sid Gilman**, University of Michigan -- Distinguished Professor of Neurology
- **Dr. David Knopman**, Mayo Clinic College of Medicine -- Professor, Department of Neurology
- **Dr. Ken Rockwood**, Dalhousie University -- Weldon Chair in Alzheimer Research, Dalhousie Medical Research Foundation
- **Dr. John Morris**, Washington University -- Harvey and Dorismae Hacker Friedman Distinguished Professor of Neurology and Director of the Memory and Aging Project

- **Dr. Eric Siemers**, Eli Lilly and Company -- Medical Director, Alzheimer's Disease Team
- **Dr. Ron Black**, Wyeth Pharmaceuticals -- Assistant Vice President of Neuroscience
- **Dr. Dale Schenk**, Elan Corporation -- Executive Vice President and Chief Scientific Officer

“These leaders in Alzheimer’s have come together because there are few things more important than evaluating treatments in early disease, even before currently recognized symptoms appear and lasting damage is done to brain function. Clear evaluation standards will inform all areas of Alzheimer’s research and will allow us to mobilize treatments in time to save the next generation,” said Howard Fillit, Howard Fillit, MD, Executive Director of the Alzheimer's Drug Discovery Foundation. “t is indeed encouraging that the FDA is collaborating with Alzheimer’s experts on this challenge both as it bears on their review of new therapies and as it sets the bar for the world’s research. We stand with the entire Alzheimer’s community in our readiness to continue this work as our number one priority.”

ACT-AD and its partners will communicate the results of today’s meeting to the Alzheimer’s community and to foster additional expert input to inform the FDA’s future work on AD. For more details on the meeting or ACT-AD’s next steps, please visit the coalition’s web site at http://www.act-ad.org/ or call 202.293.2856.

About ACT-AD
ACT-AD is a growing coalition of 50 national organizations representing patients, providers, caregivers, consumers, older Americans, researchers and employers seeking to accelerate development of potential cures and treatments for Alzheimer's. The Coalition is directed by an Advisory Council made up of representatives from Alliance for Aging Research (AAR), Alzheimer's Foundation of America (AFA), American Society on Aging (ASA), National Alliance for Caregiving (NAC), National Association of Area Agencies on Aging (n4a), National Consumers League (NCL), Research!America, and the Society for Women's Health Research. The Coalition is supported in part by educational grants from Wyeth, Elan, Pfizer, Eli Lilly, and Medivation.

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