



Accelerate Cure/Treatments for Alzheimer's Disease

**Recommendations to Develop a Roadmap to
Alzheimer's Disease Combination Therapy
Issued From Meeting of Regulatory, Industry, Research
and Funding Leaders**

***-- ACT-AD Coalition Coordinates Action Steps to Facilitate Further
Collaboration on Future R&D --***

Washington, D.C., May 30, 2013 – The ACT-AD (Accelerate Cure/Treatments for Alzheimer's Disease) Coalition, The Critical Path Institute and leaders in the Alzheimer's community today announced preliminary recommendations for a "roadmap to combination therapies for Alzheimer's disease" (AD) at the final session of a three-day event in Washington, D.C. ACT-AD Chairman, Daniel Perry, called the meeting "a vision of what is possible with interdisciplinary collaboration and commitment to defeating one of the greatest health threats of our generation, just as it has led to successful combination therapy against other complex diseases."

Following an exploratory meeting on combination clinical trials in November 2012, also coordinated by ACT-AD and the Critical Path Institute, this week's by-invitation working sessions brought together leaders from the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration, the National Institutes of Health, the academic research community, the pharmaceutical industry, private philanthropy, and patient advocacy groups to address three key areas:

- The regulatory environment following the FDA's 2010 draft guidance on unmarketed drugs for combination use;
- Adaptive clinical trial design and data sharing strategies to streamline next phases of research; and
- New approaches to leverage public/private funding for collaborative programs.

A publication detailing the recommendations will be issued by the meeting co-conveners. Mr. Perry preliminarily described the paper as "offering concrete steps toward overcoming many of the obstacles that previously kept us from taking what we learned from years of clinical trial results on drugs that alone were disappointing and efficiently studying how the right combinations may make AD treatable or even preventable." Since 2006, ACT-AD, a coalition of more than 50 national organizations seeking to accelerate better treatments and potential cures for Alzheimer's disease, has been coordinating meetings to foster successful collaboration across stakeholder groups.

Diane Stephenson, Ph.D., Executive Director of the Critical Path Institute's Coalition Against Major Diseases (CAMD), also co-host for the meeting, added that "learnings across complex diseases are what inspired the engagement of

C-Path, whose core mission is to accelerate the development of drug development tools through a regulatory path for diseases of unmet need, such as AD and tuberculosis.” “It was very encouraging to hear consensus among the FDA, researchers and the pharmaceutical industry that a new generation of clinical trials can proceed without the costly burden of duplicating past research.”

Presenters and panelists included:

- **Don Berry**, Ph.D., Berry Consultants
- **Chas Bountra**, Ph.D., University of Oxford
- **David Dilts**, Ph.D., MBA, CMA, Dilts Partners
- **Debra Hanna**, Ph.D., Critical Path Institute
- **Rusty Katz**, M.D., U.S. Food Administration
- **Steven Potkin**, M.D., University of California at Irvine
- **Reisa Sperling**, M.D., MMsc, Harvard Brigham and Women’s
- **John Trojanowski**, M.D., Ph.D., University of Pennsylvania

For more information on the Roadmap to Combination Therapies for Alzheimer’s Disease, please visit the coalition’s website at <http://www.act-ad.org/> or call 202-293-2856. To arrange an interview with Daniel Perry, please contact Harry Wade at harry.wadenyc@yahoo.com or call 917-482-9057.

About ACT-AD

ACT-AD is a coalition of more than 50 national organizations representing patients, providers, caregivers, consumers, older Americans, researchers, employers and health care industries 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. ACT-AD is supported in part by sponsorship from Bristol-Myers Squibb, Élan, Eli Lilly and Company, JANSSEN, Merck and Pfizer.

About Alzheimer’s Disease

AD is a progressive and fatal neurodegenerative disorder marked by cognitive deterioration affecting many areas of function. According to The Alzheimer’s Association, AD affects nearly 5.4 million U.S. patients, including one in eight people age 65 and nearly half of those over age 85. Members and caregivers are also impacted by the disease as they care for a vast majority of Alzheimer’s and dementia patients. Without a cure or effective treatments to delay the onset or progression of AD, it is estimated that the disease could affect over 16 million people by 2050.

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