

Pursuing Combination Therapy Development for Alzheimer's Disease
An FDA/Alzheimer's Disease Allies Meeting

**Hilton Executive Meeting Center
1750 Rockville Pike
Rockville, MD 20852**

November 29, 2012

OBJECTIVES

- Combination therapy development has been successful in other life-threatening diseases in part because collaborative approaches were established to identify necessary pathways and tools that enabled more efficient trials. Our primary goal is to explore how similar partnerships could foster more robust collaboration in Alzheimer's disease (AD) in order to encourage the development of combination therapies.
- FDA has published draft guidance on the co-development of multiple treatments for use in combination. Our second goal is to gain greater clarity of FDA's requirements for the development of multiple therapies in combination for the treatment of Alzheimer's disease and explore the feasibility of practically designing clinical trials for more than one AD therapy.

WELCOME

- 7:30– 8:00 a.m. **Registration and Continental Breakfast**
- 8:00-8:20 a.m. **Welcome**
Dan Perry, ACT-AD
Diane Stephenson, PhD, C-Path Institute

PRESENTATIONS

- 8:20-8:35 a.m. **Importance of Pre-Competitive Collaboration**
Michael Krams, MD, Janssen Pharmaceuticals
- 8:35-8:50 a.m. **Designing a Trial for Combination Therapies**
Don Berry, PhD, Berry Consultants
- 8:50-9:05 a.m. **Challenges of combination therapy in Preclinical AD Trials**
Reisa Sperling, MD, Harvard Medical School
- 9:05-9:35 a.m. **Q&A**

9:35-10:05 a.m. **Challenges with Pre-Competitive Collaboration**
David Dilts, PhD, Center for Management Research in Healthcare

10:05.-10:35 a.m. **Successful Models for Pre-Competitive Collaboration**
Debra Hanna, PhD, Critical Path to TB Drug Regimens
John McKew, MD, NIH, National Center for Advancing
Translational Sciences

10:35-11:05 a.m. **Q&A**

11:05-11:35 a.m. **Regulatory Perspectives on Combination Therapy
Development**
Bob Temple, MD, U.S. Food and Drug Administration

11:35-12:00 p.m. **Q&A**

12:00-12:15 p.m. **Break (Boxed lunch)**

PANEL

12:15-1:15 p.m. **Opportunities for Pre-Competitive Collaboration in Alzheimer's
Disease**

Discussion Leader: Allan Fox, FoxKiser

Panelists: David Dilts, PhD, Center for Management Research in Healthcare
Owen Fields, PhD, Pfizer
Rusty Katz, MD, U.S. Food and Drug Administration
Johan Luthman DDS, PhD, Merck
Diane Stephenson, PhD, C-Path Institute

- Why is pre-competitive collaboration essential to the development of combination therapies for Alzheimer's disease?
- What should our shared vision be for pre-competitive collaboration in Alzheimer's disease?
- What can we learn from models of pre-competitive collaboration in other diseases and industries?
- What are the necessary requirements to make successful pre-competitive collaboration occur? How can we build off of existing public-private partnerships? Do new partnerships need to be pursued?
- What are your top three recommendations for how we can encourage and accelerate combination therapy development for Alzheimer's disease?

1:15– 1:45 p.m. **Q&A**

CLOSING

1:45-2:00 p.m. **Concluding Remarks**
Dan Perry, ACT-AD