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

8th Annual FDA/Alzheimer's Disease Allies Meeting

Assessing the Scientific Foundation for Alzheimer's Disease Therapeutic Development

Marriott Hotel & Conference Center
5701 Marinelli Road
Bethesda, MD 20852

September 16, 2015

OBJECTIVES

On July 16, 2015, the U.S. Food and Drug Administration released a report on targeted drug therapy. This report highlighted the lack of success to date in bringing transformative therapies to market for Alzheimer's disease as well as the factors behind the robust pipelines of treatments that exist today for HIV/AIDS and cancer. FDA's report emphasized that basic information about the causes of Alzheimer's disease and pathways to slow its progression is lacking.

This meeting will take participants back to basics examining lessons from pioneering studies that incorporated Alzheimer's disease biomarkers and surrogate endpoints. Participants will also explore how genetics and processes like neuroprotection, immunity, metabolism, and inflammation are changing the conceptualization of Alzheimer's disease. The program will conclude with a candid exchange on practical considerations aimed at improving the prospects for Alzheimer's disease treatment and prevention trials such as target validation, disease models, endpoint selection and effect size.

WELCOME

9:30– 10:00 a.m. **Registration and Breakfast**

10:00-10:15 a.m. **Welcome and Introduction**
Cynthia Bens, ACT-AD

PRESENTATIONS

10:15-10:45 a.m. **What Alzheimer's disease clinical trials have revealed**
Rachelle Doody, M.D., Ph.D., Baylor College of Medicine

10:45-11:00 a.m. **Q&A**

11:00-11:30 a.m. **Changing conceptualization of Alzheimer's disease**
George Perry, Ph.D., The University of Texas San Antonio

11:30-11:45 a.m. **Q&A**

11:45-12:00 p.m. **Break**

12:00-12:20 p.m. **What we are learning about Alzheimer's disease genetics**
Bryan Traynor, M.D., Ph.D., MMSc, MRCPI**,** National Institute on Aging

12:20-12:35 p.m. **Q&A**

12:35-1:30 p.m. **Lunch**

PANEL

1:30-2:30 p.m. **Scientific and regulatory considerations for advancing pre-clinical Alzheimer's disease therapeutic development**

Panelists: Rachelle Doody, M.D., Ph.D., Baylor College of Medicine (Moderator)
Billy Dunn, M.D., U.S. Food and Drug Administration
Gabriela Lavezzari, Ph.D., MBA, PhRMA
George Perry, Ph.D., The University of Texas San Antonio
Suzana Petanceska, Ph.D., National Institute on Aging
Eric Siemers, M.D., Eli Lilly and Company
John Stofko, Biogen
Bryan Traynor, M.D., Ph.D., MMSc, MRCPI**,** National Institute on Aging

2:30– 3:30 p.m. **Q&A**

CLOSING

3:30-4:00 p.m. **Summary and Concluding Remarks**
Cynthia Bens, ACT-AD