Streamlining Phase II Clinical Trials for Alzheimer's Disease Therapies

Hilton Executive Meeting Center
1750 Rockville Pike Rockville, Maryland

November 30, 2010

8:00 a.m. **Registration and Breakfast**

WELCOME

8:30 -8:45 a.m. Welcome and Introductions

- Dan Perry, ACT-AD
- Sue Peschin, Alzheimer's Foundation of America
- Howard Fillit, Alzheimer's Drug Discovery Foundation

PRESENTATIONS

8:45 -9:00 a.m. Review of Clinical Trial Issues in Recent and Current Phase II Alzheimer's Disease Trials

- Rachelle Doody, Baylor College of Medicine

9:00-9:15 a.m. Update on Refinement of Cognitive Scales

- Jeremy Hobart, Peninsula College of Medicine and Dentistry, United Kingdom

9:15 -9:35 a.m. Update on AD Consortium Efforts to Investigate Imaging and Biomarkers

- What investigators are learning
  - Les Shaw, University of Pennsylvania
- How are discoveries becoming operationalized in clinical trials
  - Ron Black, Pfizer

PANELS

9:35 -10:35 a.m. Potential Alzheimer's Disease Phase II Trial Designs for Disease – Modifying Compounds

Discussion Leader: Rachelle Doody, Baylor College of Medicine
Participants: Martin Farlow, Indiana University School of Medicine
Howard Feldman, Bristol-Myers Squibb
Anthony Gamst, UCSD
Russell Katz, U.S. Food and Drug Administration
Rachel Schindler, Pfizer

- Translation of clinical research into clinically meaningful outcomes
  - Establishing a clinically meaningful effect recognized by regulators
- Biomarker implementation and best practices
  - Establishment of consensus in the field for endorsement of biomarkers in AD
- Principles of Phase II design to better inform Phase III
  - Other options to lengthy trial durations or endorsed biomarkers

10:35-11:00 a.m. Q&A

11:00 -12:15 p.m. Biomarkers: Purposes and Use

Discussion Leader: Reisa Sperling, Harvard, Brigham and Women's
Participants: Cliff Jack, Mayo Clinic
Dale Schenk, Elan
Les Shaw, University of Pennsylvania
Eric Siemers, Eli Lilly
Marc Walton, U.S. Food and Drug Administration

- Challenges faced in research and development
- Opportunities for changing the treatment landscape

12:15-12:45 p.m. Q&A

CLOSING

12:45-1:00pm Concluding remarks

- Dan Perry, ACT-AD