

Appendix G
2006 Cardiovascular Biomarkers and Surrogate Endpoints Symposium AGENDA

Monday, September 18th

- 11:30am – 12:00pm Registration and Buffet Lunch
- 12:00pm - 12:15pm Welcome and Conference Objectives
Dr. Jean-Claude Tardif and Dr. Therese Heinonen
- 12:15pm - 12:45pm Keynote address
Dr. Scott Gottlieb
Deputy Commissioner for Medical and Scientific Affairs
United States Food and Drug Administration
- 12:45pm - 1:15pm Pathogenesis of Atherothrombotic Disease and Biomarker identification
Dr. Peter Libby (Brigham and Women's Hospital)
- 1:15pm – 1:45pm Biomarkers in Acute Coronary Syndrome
Dr. David Morrow (TIMI Study Group, Brigham and Women's Hospital)
- 1:45pm – 2:15pm Thrombosis: New Strategies for Anti-thrombotic Therapies
Dr. Bruce Furie (Harvard Medical School)
- 2:15pm – 2:45pm Biomarkers in Diabetes, Metabolic Syndrome and Renal Disease
Dr. Steven Haffner (University of Texas Health Centers)
- 2:45pm – 3:15pm Biomarkers in Heart Failure
Dr. James De Lemos (University of Texas-Southwestern Medical School)
- 3:15pm – 3:45pm Novel Cardiovascular Biomarkers
Dr. Marc Pfeffer (Brigham and Women's Hospital)
- 3:45pm – 4:15pm Biomarkers in Cerebrovascular Disease
Dr. Pierre Amarenco (Bichat- Claude Bernard University Hospital)
- 4:15pm - 5:15pm **EXPERT PANEL DISCUSSIONS –Moderators: Peter Libby and Allan Jaffe (panelists include J.C. Tardif, D. Morrow, B. Furie, S. Haffner, J. De Lemos, M. Pfeffer, P. Amarenco, and E. Rimm)**
- Conclusion – Day 1
- 7:00pm Reception and Dinner

AGENDA

Tuesday, September 19th

- 7:30am – 8:00am Biomarker Discovery and The Challenges of Validation
Dr. Robert Gerszten (Massachusetts General Hospital)
- 8:00am – 8:30am Surrogate Endpoints in Clinical Trials
Dr. Paul Ridker (Brigham and Women's Hospital)
- 8:30am – 9:00am Markers of Dysfunctional HDL in Coronary Artery Disease
Dr. Jay Heinecke (University of Washington)
- 9:00am – 9:30am Lipoproteins and Other Related Risk Factors
Dr. H. Bryan Brewer (Cardiovascular Research Institute)
- 9:30am – 10:00am Genomic Biomarker Validation and Pharmacogenomic Initiatives at the FDA
Dr. Federico Goodsaid (FDA Office of Clinical Pharmacology)
- 10:00am – 10:30am Targeted Molecular and Cellular Imaging
Dr. Jonathan Lindner (Division of Cardiovascular Medicine)
- 10:30am – 11:30am **EXPERT PANEL DISCUSSIONS – Moderators: Philip Greenland and Paul Ridker (panelists include R. Gerszten, J. Heinecke, H. B. Brewer, F. Goodsaid, J. Lindner, J. C. Tardif, P. Libby, R. Krauss, and F. Sacks)**
- 11:30am – 12:30pm **LUNCH BREAK**
- 12:30pm – 1:00pm The Role of Imaging in Disease Detection and Treatment
Dr. Jean-Claude Tardif (Montreal Heart Institute)
- 1:00pm – 1:30pm Measures of Cardiac Structure and Function by MRI
Dr. Joao Lima (Johns Hopkins Medical School)
- 1:30pm – 2:00pm Current Status of Disease Assessment with Carotid Ultrasound
Dr. Allen Taylor (Walter Reed Army Medical Center)
- 2:00pm – 2:30pm Cardiac CT and CT/PET
Dr. Zahi Fayad (Mount Sinai School of Medicine)
- 2:30pm – 3:00pm Special Considerations Based on Gender, Age and Ethnicity
Dr. Michelle Albert (Harvard Medical School)
- 3:00pm – 3:30pm New Insights Based on Technological Advances and Landmark Trials
Dr. Robert Harrington (Duke University)
- 3:30pm – 4:30pm **EXPERT PANEL DISCUSSIONS – Moderators: Jean-Claude Tardif and Joao Lima (panelists include A. Taylor, Z. Fayad, M. Albert, R. Harrington, P. L'Allier, P. Libby, and L. Appel)**
- Conclusion – Day 2

Wednesday, September 20th

- 7:30am – 8:00am The FDA Critical Path Initiative – Opportunities and Challenges
Dr. Douglas Throckmorton (FDA Cardio-Renal)
- 8:00am – 8:30am The Need for Biomarkers in Drug Development
Dr. David G. Orloff (former FDA/Medpace)
- 8:30am – 9:00am The Use of Biomarkers for FDA Regulatory Decision Making – Metabolism and Endocrine
Dr. Mary Parks (FDA Metabolism and Endocrine)
- 9:00am – 9:30am The Use of Biomarkers for FDA Regulatory Decision Making – Cardio-Renal
Dr. Norman Stockbridge (FDA Cardio-Renal)
- 9:30am – 10:00am Canadian Regulatory View on Cardiovascular Biomarkers and Surrogate Endpoints in Clinical Trials
Dr. Timao Li (Health Canada Cardio-Renal)
- 10:00am – 10:30am European Regulatory View on Cardiovascular Biomarkers and Surrogate Endpoints in Clinical Trials
Dr. Clemens Mittmann (Federal Institute for Drug and Medical Devices)
- 10:30am – 11:00am The Use of Biomarkers for FDA Regulatory Decision Making - Health Claims
Dr. Paula Trumbo (FDA Nutrition Science Evaluation)
- 11:00am - 12:00pm **EXPERT PANEL DISCUSSIONS – Moderators: Robert Harrington and Eric Brass**
(panelists include D. Throckmorton, D. Orloff, M. Parks, N. Stockbridge, T. Li, C. Mittmann, and P. Trumbo)
- 12:00pm – 12:30pm **LUNCH BREAK**
- 12:30pm – 1 :00pm Integrating Biomarkers into Practice: The Need for Data on Clinical Outcomes
Dr. Gurveet Randhawa (US Agency for Healthcare Research and Quality)
- 1:00pm – 1:30pm Clinical Application of Biomarkers
Dr. Robert Balaban (NHLBI/NIH)
- 1:30pm – 2:00pm NIH Cardiovascular Biomarker Initiatives
Dr. Christopher O'Donnell (NHLB I/NIH)
- 2:00pm – 2:30pm The Balance Between Safety and Efficacy: Biomarkers as Safety Surrogates
Dr. Eric Brass (UCLA Medical Center)
- 2:30pm – 3:30pm **EXPERT PANEL DISCUSSIONS – Moderators: Jean-Claude Tardif and Peter Libby (panelists include G. Randhawa, R. Balaban, C. O'Donnell, E. Brass, P. Greenland, and M. Prescott)**
- 3:30pm Closing Remarks
Drs. Peter Libby and Jean-Claude Tardif