

Appendix E

2005 Cardiovascular Biomarkers and Surrogate Endpoints Symposium

Friday, September 23rd

- 8:00am – 8:20am Welcome and Conference Objectives
Dr. Jean-Claude Tardif and Dr. Therese Heinonen
- 8:20am – 8:40am Pathogenesis of Atherothrombotic Disease and Biomarker identification
Dr. Peter Libby
- 8:40am – 9:00am Is CRP a Validated Biomarker of CV Disease?
Dr. Paul Ridker
- 9:00am – 9:20am The Role of Imaging in Disease Detection and Treatment
Dr. Jean-Claude Tardif
- 9:20am – 9:40am Markers of CV Disease: Application to Clinical Practice and Public Health
Dr. Lewis Kuller
- 9:40am – 10:00am **Questions and Answers- Faculty**
- 10:00am – 10:30am **BREAK**
- 10:30am – 10:50am The Need for Biomarkers in Drug Development
Dr. Bill Sasiela
- 10:50am – 11:10am The FDA Critical Path Initiative – Opportunities and Challenges
Dr. Douglas Throckmorton
- 11:10am – 11:30am How Does the FDA Metabolism and Endocrine Department View Surrogate Endpoints?
Dr. David Orloff
- 11:30am – 12:30 pm **Questions and Answers – Faculty and PANEL DISCUSSION**
- 12:30pm – 2:00pm **LUNCH with Breakout Sessions**
- 2:00pm – 2:20pm The role of Lipoproteins in Inflammation
Dr. Philip Barter
- 2:20pm – 2:40pm Oxidation in the Pathogenesis of Atherosclerosis
Dr. Jay Heinecke
- 2:40pm – 3:00pm Special Considerations in Diabetes and Metabolic Syndrome
Dr. Steven Haffner
- 3:00pm – 3:20pm Opportunities for the use of Biomarkers and Surrogate endpoints in the European Union
Dr. Eric Abadie
- 3:20pm – 3:40pm The Balance Between Safety and Efficacy: Biomarkers as Safety Surrogates
Dr. Eric Brass

3:40pm – 4:30pm **Questions and Answers – Faculty and PANEL DISCUSSION**

Conclusion – Day 1

Saturday, September 24th

8:00am – 8:20am Summary and Introduction
Dr. Jean-Claude Tardif and Dr. Peter Libby

8:20am – 8:40am Diagnostic and Therapeutic Synergies
Dr. Donald Black

8:40am – 9:00am Current Status of Disease Assessment with Carotid Ultrasound
Dr. Allen Taylor

9:00am – 9:20am IVUS As a Surrogate Endpoint
Dr. Steve Nissen

9:20am – 9:40am Palpography and Elastography as Biomarkers of Cardiovascular Disease
Dr. Ton van der Steen

9:40am – 10:00am Advances in Cardiovascular Imaging
Dr. Minh Nguyen

10:00am – 10:30am **Questions and Answers- Faculty**

10:30am – 11:00am **BREAK**

11:00am – 11:20am Combined Blood Biomarkers: Diminishing Returns or are More Better?
Dr. Wolfgang Koenig

11:20am – 11:40am Applying Genomics, Proteomics and Metabolomics Technology to Development Programs
Dr. Michael Phillips

11:40am – 12:00pm **Questions and Answers – Faculty and PANEL DISCUSSIONS**

12:00pm – 1:30pm **LUNCH with Breakout Sessions**

1:40pm – 2:00pm **BREAK**

2:00pm – 3:10pm **Summary of 2 day Breakout Sessions (Session Leaders)**

- **How should pharmacogenomics be used prospectively in clinical studies of drug safety and efficacy?**
- **The future of diagnostics – who are the drivers?**
- **How can we maximize the application and utility of safety biomarkers?**
- **How should biomarkers be used in pre-clinical modeling and early dose selection?**

- **What is a rational approach to biomarker validation?**
- **How do you develop a drug that does not target an accepted surrogate endpoint?**
- **Vascular imaging technologies – technical and clinical considerations?**

3:10pm – 3:30pm

Questions and Answers – Faculty and PANEL DISCUSSIONS

3:30pm

Closing Remarks

Drs. Peter Libby and Jean-Claude Tardif