

S T A I R II
STROKE TREATMENT
ACADEMIC INDUSTRY ROUNDTABLE

***“Stroke Drug Development:
Improving Clinical Trial Design and Endpoint Selection”***

*Redwood City, California
Sofitel Hotel*

Conference Program

Thursday, March 9th

7:00 – 7:30 *Le CONTINENTAL BREAKFAST
Le Grande Triumph*

7:30 – 7:45 **WELCOME & OVERVIEW OF THE CONFERENCE GOALS – M. FISHER**
Bordeaux Ballroom

7:45 – 8:15 **Current Status of Acute Stroke Therapy: Thrombolysis, Neuroprotection and
Combination therapy – W. Hacke**

SESSION 1 – LESSONS FROM UNSUCCESSFUL PRIOR TRIALS – D. Easton, T. Wessel

8:15 – 8:30 **Lessons from Unsuccessful Thrombolytic Trials – T. Brott**

8:30 – 8:45 **Lessons from Unsuccessful Neuroprotective Trials – J. Grotta**

8:45 – 9:45 **Roundtable Panel Discussion “Lessons from Unsuccessful Stroke Trials”
Academic and Industry Perspectives – R. Atkinson, T. Brott, E. Gamzu, J. Grotta,
T. Furlan, W. Hacke**

9:45 – 10:00 **Break in Le Grande Triumph**

SESSION 2: PHASE II & III TRAILS FOR ACUTE ISCHEMIC STROKE
C. Hsu, J. LeClerc

10:00 – 10:15 **Industry Perspectives on Phase II & III Acute Stroke Trials – M. Bozik**

10:15 – 10:30 **Academic Perspectives on Phase II & III Acute Stroke Trial – R. Sacco**

10:30 – 10:45 **Statistical and Methodological Considerations – B. Tilley**

10:45 – 11:45 **Roundtable Panel Discussion: “Issues Related to Organizing Successful Phase II
& III Trials” Academic & Industry Perspectives – S. Frederick, M. Bozik,
D. Levy, K. Lees, R. Sacco, B. Tilley**

11:45 – 1:00 **LUNCH in La Terrasse**

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SESSION 3: REGULATORY ISSUES RELATED TO STROKE DRUG DEVELOPMENT

V. Hachinski, M. Walker

- 1:00 – 1:15** FDA Environment for Approving Acute Stroke Therapeutic Agents
E. Salazar
- 1:15 – 1:30** An Academic Perspective on the FDA Drug Approval Process – *J. Zivin*
- 1:30 – 1:45** The European Drug Agencies’ Approach to Drug Approval – *L. Bauer*
- 1:45 – 2:00** How Drug Companies Approach Regulatory Issues for Multi-national Approval
M. Humphries
- 2:00 – 2:50** ROUNDTABLE PANEL DISCUSSION: “Requirements for Drug Approval,
Academic & Industry Perspectives – *M. Kaste, J. Zivin, B. Wallin, W. Bauer,
M. Humphries, E. Salazar*
- 2:50 – 3:10** LECTURE: “*Fostering Partnerships to Promote Successful Drug Development
for Acute Ischemic Stroke*” – *L. Caplan*
- 3:10 – 3:30** BREAK in Hotel Foyer

SESSION 4: TRIAL ENDPOINTS – *P. Gorelick, T. Ashwood*

- 3:30 – 3:45** Overview of Neurological Endpoints – *L. Brass*
- 3:45 – 4:00** Functional Endpoints for Stroke Trials – *P. Lyden*
- 4:00 – 4:15** Surrogate Markers for Acute Stroke Trials – *S. Warach*
- 4:15 – 5:00** ROUNDTABLE PANEL DISCUSSION: “What are Appropriate Endpoints for
Phase II – III Trials?” *Academic & Industry Perspectives – A. Buchan, P. Lyden,
S. Warach, M. Poole, R. Meibach, L. Brass*
- 6:00 – 7:00** Cocktail Reception in *Le Grande Triumph*
- 7:00 – 8:30** Dinner in *Champagne Room*
- 8:30 – 8:45** Summation of Day One and Goals for Day Two – *S. Finklestein*

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Friday, March 10th

7:00 – 8:00 *Le BREAKFAST*
Le Grande Triumph

8:00 – 10:00 **WORKSHOPS TO DEVELOP CONSENSUS RECOMMENDATIONS**
Bordeaux Participants will be divided into three groups – each to develop recommendations

Workshop 1: Recommendations for: Appropriate Data from Phase I & II Studies, Necessary to Proceed to Phase III – *J. Bogousslavsky, J. Broderick*
Salon I

Workshop 2: Recommendations for: Designing and Implementing an Optimal Phase III trial for Acute Ischemic Stroke – *G. Albers, L. Brass*
Salon II

Workshop 3: Recommendations for: Designing a Combination Therapy Phase III Trial
Salon IV L. Goldstein, J. Zivin

10:00 – 10:45 **Break & Reconvene All Attendees**
Le Grande Triumph

10:45 – 12:00 **WORKSHOP CHAIRS PRESENT RECOMMENDATIONS from their Group with General Discussion. Begin to Draft a Consensus Statement.**
Bordeaux *Chaired by M. Fisher*

12:00 **Adjournment**

————— *Thank You for Your Participation.* —————