“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 TRIALS 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 Terrassa
“Stroke Drug Development:
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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


2:50 – 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
STAIR II
STROKE TREATMENT
ACADEMIC INDUSTRY ROUNDTABLE

“Stroke Drug Development:
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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

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

Workshop 3: Recommendations for: Designing a Combination Therapy Phase III Trial 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.  ———