STAIR V
STROKE TREATMENT
ACADEMIC INDUSTRY ROUNDTABLE

“Acute Stroke Treatment Trials:
A New Era of Regulatory, Technology and
Design Opportunities”

Arlington, VA
March 25th & 26th, 2006

STAIR V Preliminary Program

Saturday, March 25th Morning

7:00—8:00 CONTINENTAL BREAKFAST

8:00—8:40 WELCOME — OVERVIEW OF CONFERENCE GOALS & IMPACT OF PRIOR STAIRS
M. Walker & D. Easton
• Welcoming Remarks – Conference Chair – Marc Fisher
• Impact of Prior STAIR Conferences – Kennedy Lees

8:40—10:40 SESSION 1: LESSONS AND IMPLICATIONS FROM SAINT TRIALS
R. Sacco & W. Söehngen
• Detailed Overview of the SAINT 1 Results — S. Davis
• Lessons About Trial Design and Implementation from the SAINT Trials – C. Diener
• Shifting the Modified Rankin as a Primary Outcome Measure: Clinical Significance, Biological Relevance and Implications for Future Trials – J. Saver
• Impact on Future Stroke Trials if NXY-059 is Approved or Not Approved – W. Hacke
• ROUNDTABLE PANEL DISCUSSION: “Lessons and Implications”

10:40—11:00 Refreshment Break

11:00—12:45 SESSION 2: TELEMEDICINE: POTENTIAL IMPACT ON ACUTE STROKE TRIALS
& THE MARKETING OF NEWLY APPROVED THERAPIES
V. Hachinski & T. Odergren
• Telemedicine in Conjunction with a DPH Mandate for Primary Stroke Centers – E. Smith
• Enhancing IV-tPA use and newly approved stroke Therapies – D. Hess
• Models of Designing and Implementing Telemedicine-based Acute Stroke Trials – P. Lyden
• Can Telemedicine Networks Facilitate a National Stroke Consortium? – G. Albers
• ROUNDTABLE PANEL DISCUSSION: “Telemedicine Impact”
  E. Smith, D. Hess, P. Lyden, G. Albers, M. Rosenberg, M. Rymer, N. Bornstein

12:45—1:45 LUNCH PROVIDED
“Acute Stroke Treatment Trials: 
A New Era of Regulatory, Technology and Design Opportunities”

Saturday, March 25th  Afternoon

1:45—4:15 SESSION 3:  REGULATORY AND REIMBURSEMENT ISSUES
H. Adams & S. Liang
- Device Therapies: Approvals beyond MERCI – C. Pena, FDA
- FDA Regulation of Therapies and Trials Combining Drugs and Devices– M. Kramer, FDA
- The Process for Changing the DRG tPA – T. Curtis
- Harmonizing Drug and Device Approval – T. Furlan
- ROUNDTABLE PANEL DISCUSSION: “Regulatory Challenges and Insights”

4:15—4:30 Refreshment Break

4:30—6:00 SESSION 4:  CURRENT STATUS AND FUTURE PROSPECTS FOR INTERVENTIONAL DEVICES TO TREAT ACUTE STROKE
J. Bogousslavsky & B. Skolnick
- Endovascular Approaches to Clot Removal and Dissolution – T. Tomsick
- Inducing Hypothermia and Enhancing Collateral Flow – R. Atkinson
- Combining Intravenous and Intra-Arterial Delivery of Drugs and Devices: The Ultimate Future Combination Therapy? – J. Broderick
- ROUNDTABLE PANEL DISCUSSION: “Devices to Treat Acute Stroke”
  T. Tomsick, R. Atkinson, J. Broderick, M. Kaste, A. Weiss, L. Wechsler, A. Wakhloo

6:30—7:00 SPONSORED COCKTAIL RECEPTION

7:00—9:00 DINNER  Master of Ceremonies – Rick Atkinson
  Keynote Address Following Dinner – STOP Stroke Bill – Caya B. Lewis
  Deputy Staff Director for Health
  Senate Health, Education, Labor and Pensions Committee
  United States Congress
All Participants: Please Convene in the Laurel Room Prior to Going to Your Workshop

Workshop 1: Recommendations for Design:
Novel Approaches to Measuring Outcomes in Phase II & III Acute Stroke Trials
Red
S. Warach, P. Gorelick, G. Howard

Workshop 2: Recommendations for Technology:
Incorporating New Technology into Trials: Telemedicine, Electronic databases/CRFs, Blue and Population Kinetics in Acute Stroke Drug/Device Development
L. Goldstein, J. Marler, E. Jauch

Workshop 3: Recommendations for Regulatory:
Proceeding into the Combination Therapy Era of Drugs + Drugs and Drugs + Devices
Green D. Hanley, W. Smith, A. Quereshi

10:30 – 11:00 Refreshment Break

11:00—12:15 WORKSHOP CHAIRS PRESENT RECOMMENDATIONS from their group with general discussion. Drafting of consensus statement is initiated.
Chaired by M. Fisher

12:15—12:30 CLOSING COMMENTS AND ADJOURNMENT

Thank You for Your Participation