

STAIR VII
STROKE TREATMENT
ACADEMIC INDUSTRY ROUNDTABLE

September 11 & 12, 2010
Arlington, Virginia

**“Designing Acute Stroke Therapy
For A New Decade”**

STAIR VII Program

Saturday Morning

7:00 – 8:00 **FULL BREAKFAST PROVIDED**
Concourse Ballroom – Main Floor of Hotel

Galaxy Ballroom – 16th Floor – All Meeting Sessions for the day are in Galaxy Ballroom

8:00 – 8:45 **INTRODUCTION AND KEYNOTE ADDRESS**

Session Co-Chairs: Vladimir Hachinski & John Hallenbeck

- Welcome from the Conference Chair – *Greg Albers*
- Perspectives about STAIR and *Stroke* – *Marc Fisher*
- Keynote Lecture: The New Decade: Priorities and Opportunities for Acute Brain Ischemia Research
– *James Grotta*

8:45 – 10:30 **SESSION 1: IMPLEMENTATION & IMPACT of IV THROMBOLYSIS BEYOND 3 HRS**

Session Co-Chairs: Susan Begelman, & Bruce Coull

- Benefits and Risk of IV Thrombolysis in 3-6 hr. Window – *Kennedy Lees*
 - Use of tPA in Clinical Practice Beyond 3 Hrs: Market Penetration – Guidelines – Regulatory Approval
– *Dawn Kleindorfer*
 - Role of Advanced *MR* Imaging for Patient Selection Beyond 3 Hours – *Steve Warach*
 - Role of Advanced *CT* Imaging for Patient Selection Beyond 3 Hours – *Maarten Lansberg*
- ROUNDTABLE PANEL DISCUSSION: “CAN WE INCREASE UTILIZATION OF IV THROMBOLYSIS?”**
John Marler & Max Wintermark

10:30 – 10:45 **REFRESHMENT BREAK** *Foyer Outside Galaxy Ballroom*

10:45 – 12:30 **SESSION 2: NON-PHARMACOLOGIC REPERFUSION STRATEGIES**

Session Co-Chairs: Helmi Lutsep & Maria Sainz

- Current Status of Intra-Arterial Reperfusion Therapy: New Data, Markets & Reimbursement
– *Wade Smith*
- Role of neuroimaging prior to intra-arterial therapy – *Mike Lev*
- Clinical Trials Using Mechanical Clot Retrievers: How Will We Determine Which Patients Benefit?
– *Tudor Jovin*
- The SENTIS Trial: A Randomized Trial of a Mechanical Device – *Andy Weiss*

ROUNDTABLE PANEL DISCUSSION: “HOW WILL WE OPTIMIZE THESE TYPES OF THERAPIES?”
Andrei Alexandrov, Arani Bose, Michael Marks, Thomas Kent

12:30 – 1:30 **LUNCH PROVIDED** **Concourse Ballroom – Main Floor of Hotel**

S T A I R V I I
STROKE TREATMENT
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Saturday Afternoon

Galaxy Ballroom – 16th Floor

1:30 – 3:30 SESSION 3: CHALLENGES FOR BRAIN ISCHEMIA RESEARCH DUE TO REGULATORY AND REIMBURSEMENT DECISIONS

Session Co-Chairs: Jackson Streeter & Joe Broderick

- **Considerations on Harmonizing FDA Device and Drug Approval Requirements – Billy Dunn**
- **Devices in Acute Stroke: Paths to Market – Natalie Getzoff**
- **How Can Clinical Trials Compete with Unproven but Reimbursed Devices? – Tony Furlan**

ROUNDTABLE PANEL DISCUSSION: PRIORITIES AND OPPORTUNITIES

Thomas Barker, Avinoam Dayan, Malvina Eydelman, Ruchir Sehra & Marc Walton

3:30 – 3:45 REFRESHMENT BREAK Foyer Outside Galaxy Ballroom

3:45 – 5:30 SESSION 4: NEUROPROTECTANTS FOR A NEW DECADE

Session Co-Chairs: Harvey Altman & Justin Zivin

- **Acute Neuroprotective Strategies: Most Promising Agents Ready for Translation – Eng Lo**
- **Why We Shouldn't Abandon Neuroprotective Strategies – Sean Savitz**
- **Neuroprotection to Prolong the Penumbra – Jeff Saver**
- **Pharmacologic Agents to Enhance Recovery – Steve Cramer**

ROUNDTABLE PANEL DISCUSSION:

Giora Feuerstein, Frank Sharp, Tom Jacobs & Mike Tymianski

6:30 – 7:00 SPONSORED RECEPTION – Sponsored by BioClinica

Assembly Foyer – Main floor – Outside Commonwealth Ballroom

7:00 – 9:00 DINNER – Followed by Entertainment by Participants

Cavalier Ballroom – Main Floor of Hotel

STAIR VII

STROKE TREATMENT
ACADEMIC INDUSTRY ROUNDTABLE

Sunday Morning, September 12

7:00 – 8:00 **BREAKFAST PROVIDED**
Concourse Ballroom – Main Floor of Hotel

All Participants: Please Report Directly to Your Assigned Workshop at 8:00 AM

8:00 – 10:30 **WORKSHOPS TO DEVELOP CONSENSUS RECOMMENDATIONS**
Participants are divided into three groups – each to develop recommendations

WORKSHOP 1: RECOMMENDATIONS FOR IV THROMBOLYSIS:

Cavalier A **Optimizing the Use of IV Thrombolysis**
Main Floor **Facilitators: *Larry Goldstein (Chair), Karen Furie & Phil Gorelick***

Considerations:

- How do we maximize utilization of IV rt-PA?
- How do we find out which patients are most and least likely to benefit, especially in the 3-4.5 hour window?
- What are the advantages and disadvantages of the available techniques to select patients for late therapy (PWI/DWI, CTP, vessel occlusion, optimized clinical criteria)?
- What are the optimal study designs to expand the treatment window?
- Is a placebo still appropriate in a 3-4.5 hr time window study or should rt-PA be the standard therapy?
- Is the Primary Stroke Center concept working? How can it be improved?

WORKSHOP 2: RECOMMENDATIONS FOR MECHANICAL REPERFUSION

Cavalier B&C **Establishing the Efficacy of Mechanical Reperfusion Therapies**
Main Floor **Facilitators: *Larry Wechsler (Chair), David Liebeskind & Raul Nogueira***

Considerations:

- What are the most important IA therapy questions to answer: how to prove efficacy?
 - Which pts. benefit and which may be harmed? – Clarify how to optimally select pts? – Clarify time window?
 - How to measure efficacy? – How to define reperfusion and SICH? – Should intubation be discouraged?
- Propose some feasible study designs, both randomized and non-randomized which address these issues.
- Discuss the statistical considerations for these study designs.
- Should the FDA mandate a randomized efficacy trial of mechanical clot removal?
- Should IV therapy be compared with IA therapy in the > 3 hr window?

WORKSHOP 3: RECOMMENDATIONS FOR PROMISING NEUROPROTECTION APPROACHES

North 1 **New Strategies To Achieve Proof Of Efficacy**
Main Floor **Facilitators: *David Hess (Chair), Patricia Hurn & Jeff Saver***

Considerations:

- Which neuroprotective strategies are most likely to be effective in humans for acute therapy?
- Which neuroprotective strategies are most likely to be effective in humans for enhancing recovery?
- Which changes in study design are most important to facilitate a positive trial in humans?
- Are there new paradigms to consider for neuroprotection to consider, i.e. penumbral extension and treating reperfusion injury?

10:30 – 10:45 **REFRESHMENT BREAK** **Assembly Foyer – Main floor – Outside Commonwealth Ballroom**

10:45 – 12:00 **WORKSHOP CHAIRS PRESENT RECOMMENDATIONS – General Discussion**
Galaxy Ballroom **Drafting of consensus statement is initiated – *Chaired by Greg Albers***

12:00 – 12:15 **CLOSING COMMENTS AND ADJOURNMENT**