

STEPS

STEM CELL THERAPIES AS AN
EMERGING PARADIGM IN STROKE

“Bridging Basic and Clinical Science for Cellular and Neurogenic Factor Therapy in Treating Stroke”

October 27th & 28th 2007

*Sheraton National Hotel
900 South Orme Street
Arlington, Virginia*

STEPS Program

Saturday, October 27th Morning

7:00— 8:00 **CONTINENTAL BREAKFAST PROVIDED**
Commonwealth North 2 Ballroom – Main Floor of Hotel Aft of Lobby

All Sessions for the day are in the Commonwealth Ballroom North 1 Room on the Main Floor of the Hotel

8:00— 8:40 **WELCOME — OVERVIEW OF CONFERENCE GOALS**

- Welcoming Remarks – Conference Co-Chairs – *Dennis Steindler & Larry Wechsler*
- Impact of Prior STAIR Conferences – *Marc Fisher*

8:40—10:40 **SESSION 1: MECHANISMS OF ACTION OF CELL THERAPY FOR STROKE**
Marc Fisher & R.W. Mays

- Cell Replacement – *Brent Reynolds*
- Neurohumoral/Trophic Affects– *Sam Weiss*
- Combining Stem Cell and Gene Therapies– *Evan Snyder*
- The Role of Imaging in Determining the Mechanism of Benefit– *Michael Weiss*
- **ROUNDTABLE PANEL DISCUSSION: “Current Hypotheses and Future Directions”**
Brent Reynolds, Sam Weiss, Michael Weiss, Marc Fisher, RW Mays, Casey Case

10:40—11:00 **REFRESHMENT BREAK** *Commonwealth North 2*

11:00—1:00 **SESSION 2: TRANSLATING ANIMAL MODELS TO HUMAN STROKE**
Evan Snyder & Paul Sanberg

- Lessons from Animal Models of Cell Therapy for Stroke – *Michael Chopp*
- Outcomes of Cell Therapy in Animal Model of Stroke – *Tom Carmichael*
- What We Need to Know From Animal Models of Stroke Before Starting Clinical Trials – *Jack Parent*
- What Can We Learn from Clinical Trials That We Can’t Learn from Animal Models– *Lou Caplan*
- **ROUNDTABLE PANEL DISCUSSION: “Translational Milestones and Goals”**
Michael Chop, Tom Carmichael, Evan Snyder, Lou Caplan, Paul Sanberg, Jack Parent

1:00—2:00 **LUNCH PROVIDED** *Commonwealth North 2*

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Saturday, October 27th Afternoon

2:00—4:00 SESSION 3: DESIGNING CLINICAL TRIALS

Sean Savitz & John Sinden

- **Choosing the Best Cell Type for Treatment** – *Sean Savitz*
- **Optimizing Cell Delivery and Host Factors** – *Cesar Borlongan*
- **Augmentation of Endogenous Stem Cells** – *Olle Lindvall*
- **Preclinical Considerations for Cell-based Therapies for Stroke** – *Mercedes Serabian, FDA*
- **Product, Manufacturing and other Considerations for Cell-based Stroke Therapies** – *Thomas Finn, FDA*
- **ROUNDTABLE PANEL DISCUSSION: “Optimizing Clinical Trial Design”**
*Bo Norrving, John Sinden, Sean Savitz, Cesar Borlongan, Leslie Gonzalez-Rothi,
Olle Lindvall, Thomas Finn, Mercedes Serabian*

4:00—4:15 REFRESHMENT BREAK Commonwealth North 2

4:15—6:00 SESSION 4: CLINICAL TRIALS OF STEM CELL/MOLECULAR THERAPIES TO DATE

David Hess & Alan Davidoff

- **Preclinical Evaluation of Autologous Bone Marrow Cell Therapy for Stroke in a Novel Large Animal Model** – *Johannes Boltze*
- **Mesenchymal Cell Studies and Other Non-neuronal Cells** – *David Hess*
- **Neuronal Cell Trials** – *Doug Kondziolka*
- **Molecular and Protein Therapeutic Trials** – *Gary Steinberg*
- **ROUNDTABLE PANEL DISCUSSION: “Lessons and Implications for Future Trials”**
*David Hess, Doug Kondziolka, Gary Steinberg, Alan Davidoff, Johannes Boltze, Robert Deans,
Thomas Finn -NINDS*

6:30—7:00 SPONSORED COCKTAIL RECEPTION Commonwealth North 2

7:00—9:00 DINNER Commonwealth North 2

Keynote Address Following Dinner

----- **Jeffrey Karan** -----

Senior Partner – Proteus Venture Partners

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Day 2

Sunday, October 28th Morning

7:30—8:30 ***BREAKFAST PROVIDED Commonwealth North 2***
Summary of Status of Companies/Technologies in Treating Stroke

- Athersys, Inc.
- ReNeuron
- San-Bio
- Stem Cell Therapeutics

All Participants: Please Convene in Commonwealth North 1 Prior to Going to Your Workshop

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

Workshop 1: Recommendations for Improved Pre-Clinical Model Design:
Commonwealth North 1 **Remaining Questions and Cell Tracking Development**
Red Badge ***Cesar Borlongan & Michael Chopp***

Workshop 2: Recommendations for Technology:
Mezzanine 2 **Route of Delivery/Delivery Devices/Dosing**
Blue Badge ***Sean Savitz and Robert Deans***

Workshop 3: Recommendations for Clinical Trial Design:
Mezzanine 3 **Outcome Measures/Role of Rehab/Safety Issues**
Green Badge ***Lou Caplan & David Hess***

10:30 – 11:00 ***REFRESHMENT BREAK Commonwealth North 2***

11:00—12:15 **WORKSHOP CHAIRS PRESENT RECOMMENDATIONS from their group with**
Commonwealth North 1 **general discussion. Drafting of consensus statement is initiated.**
Chaired by Dennis Steindler & Larry Wechsler

12:15—12:30 **CLOSING COMMENTS AND ADJOURNMENT**

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