

AMERICAN SOCIETY FOR EXPERIMENTAL NEUROTHERAPEUTICS

ASENT

14th Annual Meeting

February 22-25, 2012

The Ritz-Carlton
Washington, D.C.

Vision Statement

To advance the science of neurotherapeutics and
to improve and accelerate the development
of new treatments.

PROGRAM BOOK



American Society for Experimental
NeuroTherapeutics, Inc.

342 North Main Street, Suite 301
West Hartford, CT 06117-2507

Phone: 860-586-7570 • Fax: 860-586-7550 • Email: info@asent.org

ASENT Corporate Partners

List produced on February 8, 2012.

Emerald
\$75,000+

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Diamond
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\$25,000 - \$49,999

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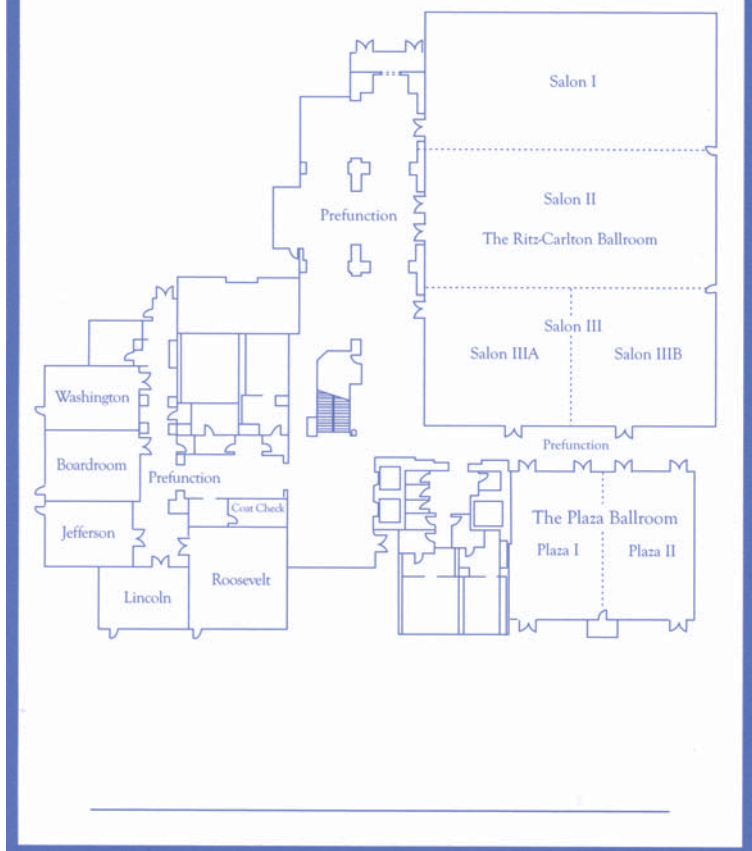
Chase Pharmaceuticals Corporation
Circuit Therapeutics
Key Neurosciences

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THE RITZ-CARLTON®
WASHINGTON D.C.



Information Exchange and Poster Presentations

Wednesday, February 22, 2012

Joint Information Exchange and Poster Presentation
Reception with ISCTM

6:00 p.m. - 8:00 p.m.

The Ritz-Carlton Ballroom, Salon III

Authors Present

Since 1999, ASENT has sponsored a poster session of new and previously unpublished data from physicians, researchers and this industry in the field of neurotherapeutics. All posters are peer reviewed and accepted posters will also be published in ASENT's journal, *Neurotherapeutics*[®]. These abstracts are also printed in this program book.

In addition, previously published data, preliminary data and/or previously reviewed posters are also welcome. These posters will not be found in the program book and will not be published in the journal.

The poster session is an opportune time for academicians to showcase potential therapeutic opportunities to the industry and for the industry to provide review data on the progress of their approved or unapproved therapies. Join us in the poster session, and meet the presenters and discuss their projects.

(See the Abstract Descriptions handout available at the Information Exchange.)

Information Tables

(Thursday, February 23 – Friday, February 24)

INC Research

KAI Research Inc.

Parkinson's Disease Foundation

Springer Science

Fink Fellowship

In 2004, ASENT established a fellowship in the name of J. Stephen Fink, MD, PhD. This fellowship commemorates his professional career and contributions to neurotherapeutics, neuroscience and neurological training. Dr. Fink served as a founding member of the Society, an executive board member and program chair of the Fifth Annual Meeting.

The American Society for Experimental NeuroTherapeutics

**is pleased
to announce the**

2012 J. Stephen Fink, MD, PhD Fellow

Amy-Lee Bredlau, MD

For the abstract entitled:

“Phase I Study of Oral Ketamine for
Control of Chronic Pain in Children”

Dr. Bredlau will receive an honorarium for submitting the best scientific abstract by a fellow-in-training for presentation at ASENT's 14th Annual Meeting.

Program Schedule

WEDNESDAY, FEBRUARY 22, 2012

6:00 p.m.-8:00 p.m.
*The Ritz-Carlton
Ballroom, Salon III*

Joint Information Exchange and
Poster Presentation Reception
with ISCTM

THURSDAY, FEBRUARY 23, 2012

Joint Scientific Session Day with ISCTM

8:00 a.m.-Noon
*The Ritz-Carlton
Ballroom, Salon I & II*

Challenges and Opportunities in
Pediatric Drug and Device Development
for NeuroPsychiatric Diseases:
A Cross-Disciplinary Symposium

Program

Co-Chairs: For ASENT: Shaun Comfort, MD, MBA, Adaptix Clinical Solutions LLC; Bennett Lavenstein, MD, Children's Hospital Medical Center; Jill Rasmussen, MD, Psi-Napse; For ISCTM: Richard Keefe, PhD, Duke University; Atul Mahableshwarkar, MD, Takeda Global Research & Development Inc.; Steve Romano, MD, Pfizer, Inc.

- | | |
|-----------------------|---|
| 8:00 a.m. – 8:05 a.m. | ■ Presidential Welcome
Robert Hamill, MD, University of Vermont;
Richard Keefe, PhD, Duke University Medical Center |
| 8:05 a.m. – 8:10 a.m. | ■ Session Objectives
Atul Mahableshwarkar, MD, Takeda Global Research & Development Inc. |
| 8:10 a.m. – 8:30 a.m. | ■ Introductory Remarks
Thomas Insel, MD, National Institute of Mental Health |
| 8:30 a.m. – 8:50 a.m. | ■ Therapeutics of the Developing Nervous System: Epilepsy as a Model
Gregory Holmes, MD, Dartmouth-Hitchcock Medical Center |
| 8:50 a.m. – 9:10 a.m. | ■ Specific Consideration for Development in Children and Adolescents: Depression as a Model
John March, MD, MPH, Duke Clinical Research Institute |
| 9:10 a.m. – 9:30 a.m. | ■ Questions and Answers |
| 9:30 a.m. – 9:45 a.m. | Break |

Program Schedule (Continued)

THURSDAY, FEBRUARY 23, 2012

- 9:45 a.m. – 10:25 a.m. ■ **Unique Challenges in Pediatric Drug and Device Development**
Bennett Lavenstein, MD, Children's Hospital Medical Center; David Michelson, Merck
- 10:25 a.m. – 10:40 a.m. ■ **Questions and Answers**
- 10:40 a.m. – 11:10 a.m. ■ **Regulatory Perspective on Pediatric Drug and Device Development**
Tiffany Farchione, MD, FDA;
Kristen Bowsher, PhD, FDA
- 11:10 a.m. – 11:25 a.m. ■ **PMDA Perspective**
Yoshiaki Uyama, PhD, Pharmaceuticals and Medical Devices Agency
- 11:25 a.m. – 11:35 a.m. ■ **Differences from EMA Perspective**
Karl Broich, MD, BfArM Germany
- 11:35 a.m. – 12:00 p.m. ■ **Questions and Answers**
- Noon – 1:30 p.m. Lunch (*The Ritz-Carlton Ballroom, Salon III*)

Break-Out Sessions (Select a Topic)

- 1:30 p.m. – 2:45 p.m. ■ **Topic 1: Specific Challenges, PK/PD, Potential for Longer Term Effects**
John March, MD, MPH, Duke Clinical Research Institute
- **Topic 2: Animal Models for Diseases, Drugs & Devices**
Gregory Holmes, MD, Dartmouth-Hitchcock Medical Center
- **Topic 3: Pediatric Outcomes and Scales**
Joseph Horrigan, MD, Autism Speaks
- **Topic 4: IRB and Ethics**
Joan Conry, MD, Children's National Medical Center; Barbara Karp, MD, NIH/NINDS
- 2:45 p.m. – 3:15 p.m. Break
- 3:15 p.m. – 5:30 p.m. **Report Back and Discussion**
The Ritz-Carlton Ballroom, Salon I & II
- **Topic 1** (3:15 p.m. – 3:45 p.m.)
- **Topic 2** (3:45 p.m. – 4:15 p.m.)
- **Topic 3** (4:15 p.m. – 4:45 p.m.)
- **Topic 4** (4:45 p.m. – 5:15 p.m.)
- **Summary and Next Steps** (5:15 p.m. – 5:30 p.m.)

Program Schedule (Continued)

THURSDAY, FEBRUARY 23, 2012

5:45 p.m.-6:45 p.m. <i>Ballroom Foyer</i>	Reception
6:45 p.m.-8:45 p.m. <i>The Ritz-Carlton Ballroom, Salon I & II</i>	Dinner Session: Product Coverage — Medical Reimbursement and Changes for the Future

Program

Co-Chairs: Mitchell Brin, MD, Allergan, Inc.; Kathleen Clarence-Smith, MD, PhD, KM Pharmaceutical Consulting LLC

- Sir Michael Rawlins, NICE
- J. Sanford Schwartz, MD, Wharton School of the University of Pennsylvania

FRIDAY, FEBRUARY 24, 2012

8:30 a.m.-11:45 a.m. <i>The Ritz-Carlton Ballroom, Salon I</i>	How Functional Brain Imaging Can Help Speed Drug Development and Clinical Trials
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Program

Co-Chairs: C. Anthony Altar, PhD, AssureRx Health, Inc; Jesse Cedarbaum, MD, Cytokinetics, Inc.; William Theodore, MD, NIH

- | | |
|-------------------------|---|
| 8:30 a.m. – 8:40 a.m. | ■ Welcome and Introduction
William Theodore, MD, NIH |
| 8:40 a.m. – 9:05 a.m. | ■ Pre-clinical Trials in Schizophrenia
Dean Wong, MD, Johns Hopkins Medical
Institutions |
| 9:05 a.m. – 9:30 a.m. | ■ Multiple Sclerosis
Richard Rudick, MD, Cleveland Clinic |
| 9:30 a.m. – 9:55 a.m. | ■ Parkinson's Disease
David Eidelberg, MD, Feinstein Institute for
Medical Research |
| 9:55 a.m. – 10:20 a.m. | ■ Depression
Helen Mayberg, MD, Emory University |
| 10:20 a.m. – 10:30 a.m. | Break |
| 10:30 a.m. – 10:55 a.m. | ■ Data Reduction: Alzheimer's
James Brewer, MD, PhD, University of
California, San Diego |
| 10:55 a.m. – 11:45 a.m. | ■ Panel Discussion |

Program Schedule (Continued)

FRIDAY, FEBRUARY 24, 2012

Noon-2:00 p.m.
*The Ritz-Carlton
Ballroom, Salon II*

Special Interest Topics and Luncheon

Program

Chair: Christopher Gallen, MD, PhD, Zalicus Inc.

- Abbreviated INDs
- Challenges to Young Researchers Entering the Field of Neurotherapeutics
- Challenges to Start-up Companies
- Challenges to International Development
- Clinical Trials: Patient Recruitment and Obstacles
- How Much Safety Must We Have?
- Measurement of Comparative Effectiveness
- Outcome Measures

2:15 p.m.-6:00 p.m.
*The Ritz-Carlton
Ballroom, Salon I*

Pipeline Session

Program

Co-Chairs: Philip Perera, MD, Helicon Therapeutics, Inc.;
Michael Rogawski, MD, PhD, University of California, Davis

Investigators in academia, government, industry and advocacy present an update on research and development progress on a specific project in the broad area of neurotherapeutics. Such projects may address neurological disorders, psychiatric disorders, pain, neurooncology, neurological infections or any other disorder affecting the central or peripheral nervous systems.

Program Schedule (Continued)

SATURDAY, FEBRUARY 25, 2012

8:30 a.m.-9:00 a.m.

*The Ritz-Carlton
Ballroom, Salon I*

ASENT Annual Meeting

9:00 a.m.-12:15 p.m.

*The Ritz-Carlton
Ballroom, Salon I*

**Academic Investigators' Symposium:
Early Drug Development**

Program

Co-Chairs: Mitchell Brin, MD, Allergan, Inc.; Roger J. Porter, MD, University of Pennsylvania; Michael Rogawski, MD, PhD, University of California, Davis; Barbara Slusher, PhD, MBA, Johns Hopkins Brain Science Institute

9:00 a.m. – 9:05 a.m.

■ **Welcome and Overview**

Mitchell Brin, MD, Allergan, Inc.

9:05 a.m. – 9:30 a.m.

■ **Overview of Early Drug Development in Neurological Disease**

Michael Rogawski, MD, PhD, University of California, Davis

9:30 a.m. – 9:35 a.m.

■ **Questions and Answers**

9:35 a.m. – 9:55 a.m.

■ **The New Paradigm of Academic Drug Discovery**

Barbara Slusher, PhD, MBA, Johns Hopkins Brain Science Institute

9:55 a.m. – 10:00 a.m.

■ **Questions and Answers**

10:00 a.m. – 10:20 a.m.

Coffee Service Available

10:20 a.m. – 10:45 a.m.

■ **Speaker to Be Announced**

10:45 a.m. – 10:50 a.m.

■ **Questions and Answers**

11:00 a.m. – 11:45 a.m.

■ **A Chemist's View of a 'Druggable' Target for CNS Disorders**

Takashi Tsukamoto, PhD, Johns Hopkins Brain Science Institute

11:45 a.m. – 12:00 p.m.

■ **Questions, Answers and Discussion**

12:00 p.m. – 12:15 p.m.

■ **What Have We Not Discussed?:
The Next Steps Toward the Clinic**

Roger J. Porter, MD, University of Pennsylvania

12:15 p.m.

Meeting Concludes

Annual Business Meeting

All members are welcome!

**Saturday, February 25, 2012
The Ritz-Carlton, Washington, D.C.**

The Ritz-Carlton Ballroom, Salon I

8:30 a.m. - 9:00 a.m.

Preliminary Agenda

- I. Call to Order
- II. Financial Report
- III. *Neurotherapeutics*[®] Journal Report
- IV. Membership Report
- V. 15th Annual ASENT Meeting,
February 28 – March 2, 2013
- VI. Recognition of Outgoing Board Members
- VII. Introduction of Incoming Board Members
- VIII. Adjournment

Meeting Evaluation/ How Do I Obtain CME Credits?

To obtain a CME certificate for the ASENT 14th Annual Meeting, please access the online evaluation on our website, www.asent.org. A link to the evaluation is on the homepage. Evaluations must be completed by March 23, 2012 in order to receive credit.

ASENT's 14th Annual Meeting has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the University of Vermont and the American Society for Experimental NeuroTherapeutics. The University of Vermont is accredited by the ACCME to provide continuing medical education for physicians.

The University of Vermont designates this live activity for a maximum of 17 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Your number of credits will be determined based on the questions you answer in the online evaluation.

Continuing Medical Education Statement and Session Objectives

Session Objectives: At the completion of the meeting, participants will be able to:

- Recognize the specific considerations for development to treatment for depression in children and adolescents;
- Describe the unique challenges in pediatric therapeutic device development; and
- Discuss the role of neuroimaging techniques in neurotherapeutics development.

Meeting Disclaimer: Regarding written materials and information received, written or otherwise, during this activity: The scientific views, statements and recommendations expressed during this CME activity represent those of the authors and speakers, and do not necessarily represent the views of the University of Vermont.

Interest Disclosures: As an organization accredited by the ACCME to sponsor continuing medical education activities, The University of Vermont is required to disclose any real or apparent conflicts of interest (COI) that any speakers may have related to the content of their presentations.

The University of Vermont requires that each speaker participating in a program designated for AMA Physician's Recognition Award Category 1 credit disclose any financial interest/arrangement or affiliation with a corporate organization that may impact on his/her presentation (i.e. grants, research support, honoraria, member of speakers' bureau, consultant, major stock shareholder, etc.)

No Interests to Disclose:

C. Anthony Altar, PhD**
Kristen Bowsher, PhD
Mitchell Brin, MD**
Karl Broich, MD
Jesse Cedarbaum, MD**
Joan Conry, MD
David Eidelberg, MD
Tiffany Farchione, MD
Christopher Gallen, MD, PhD**
Robert Hamill, MD**
Joseph Horrigan, MD
Thomas Insel, MD
Barbara Karp, MD
Bennett Lavenstein, MD**

Atul Mahableshwarkar, MD
David Michelson, MD
Philip Perera, MD**
Jill Rasmussen, MD**
Michael Rawlins, MD
Michael Rogawski, MD, PhD**
Richard Rudick, MD
J. Sanford Schwartz, MD
Barbara Slusher, PhD, MBA
William Theodore, MD**
Takashi Tsukamoto, PhD
Yoshiaki Uyama, PhD
Dean Wong, MD, PhD

(Continued)

Continuing Medical Education Statement and Session Objectives

Interests to Disclose/COI/Bias Resolved*:

James Brewer, MD, PhD

Lilly Biomarker Business Unit; Advisory Board
Janssen Alzheimer Immunotherapy

Gregory Holmes, MD

Eisai; Data Safety Monitoring Board
Sunovion, Teva, Questcor and Lundbeck: Consultant

Kathleen Clarence-Smith, MD**

Lundbeck, Chase Pharmaceuticals Corporation, Key Neurosciences SAS, CSK
Consulting LLC, NC Medical, BHR Pharma LLC, KLS Partners: Consultant

Shaun Comfort, MD**

Pharma and Device Companies: Consultant

Richard Keefe, PhD

Abbott, Amgen, Astellas, Asubio, BiolineRx, Cypress Bioscience, Eli Lilly,
EnVivo, Lundbeck, Pfizer, Roche, Shire, Sunovion, Takeda: Consulting/Ad Board
Department of Veteran's Affairs, GSK, NIMH, Novartis, PsychoGenics,
Research Foundation for Mental Hygiene, Inc., Singapore Medical Research
Council; Research Funding Brief Assessment of Cognition in Schizophrenia,
MATICS Battery; Royalties

John March, MD, MPH

MedAvante: Equity
Alkermes, Inc., Attention Therapeutics, Avanir, BMS, Lilly, Pfizer, Psymetrix,
Scion, Shire, Translational Venture Partners, LLC, Trevena, Widay
Pharmaceuticals, LLC, Vivus: Scientific Consulting Fees
Guildford Press, MultiHealth Systems, Oxford University Press: Royalties

Helen Mayberg, MD

St. Jude Medical Neuromodulator, Inc.: Consultant, Licensing of IPTO

Roger J. Porter, MD**

Neuropace, Eli Lilly, GSK, Valeant, Axcan, Upsher-Smith, Lundbeck, Knopp,
Salamandra, Tolo, Zalicus: Consultant

* Having a financial interest or other relationship with a corporate organization may not prevent a speaker from making a presentation; however, the existence of the relationship must be made known to the planning committee prior to the conference so that any possible conflict of interest may be resolved prior to the talk.

** ASENT Program Committee

14th Annual Meeting Program Committee

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AssureRx Health Inc.

Mitchell Brin, MD
Allergan, Inc.

Jesse Cedarbaum, MD
Cytokinetics, Inc.

Kathleen Clarence-Smith, MD, PhD
KM Pharmaceutical Consulting, LLC

Shaun Comfort, MD, MBA
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University of Pennsylvania

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Research

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Psi-Napse

Richard Rudick, MD
Cleveland Clinic

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KM Pharmaceutical Consulting, LLC

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Notes



FUTURE MEETINGS

ASENT 15th Annual Meeting

February 28 – March 2, 2013

Hyatt Regency Bethesda

Bethesda, Maryland

Abstract submissions begin
June 1, 2012

Schedule-At-A-Glance

WEDNESDAY, FEBRUARY 22, 2012

5:00 p.m. – 8:00 p.m.
The Ballroom Foyer Registration

6:00 p.m. – 8:00 p.m.
The Ritz-Carlton Ballroom, Salon III Joint Information Exchange and Poster Presentation Reception with ISCTM

THURSDAY, FEBRUARY 23, 2012

7:30 a.m. – 6:00 p.m.
The Ballroom Foyer Registration
(Continental Breakfast 7:30 a.m. – 8:00 a.m.)

Joint Scientific Session Day with ISCTM

8:00 a.m. – Noon
The Ritz-Carlton Ballroom, Salon I & II Challenges and Opportunities in Pediatric Drug and Device Development for Neuro-Psychiatric Diseases: A Cross-Disciplinary Symposium

Noon – 1:30 p.m. Lunch

1:30 p.m. – 2:45 p.m. Break-Out Sessions

2:45 p.m. – 3:15 p.m. Break

3:15 p.m. – 5:30 p.m.
The Ritz-Carlton Ballroom Salon I & II Break-Out Sessions Report Back and Discussion

5:45 p.m. – 6:45 p.m.
Ballroom Foyer Reception

6:45 p.m. – 8:45 p.m.
The Ritz-Carlton Ballroom, Salon I & II Dinner Session: Product Coverage — Medical Reimbursement and Changes for the Future

FRIDAY, FEBRUARY 24, 2012

8:00 a.m. – 6:00 p.m.
The Ballroom Foyer Registration
(Continental Breakfast 8:00 a.m. – 8:30 a.m.)

8:30 a.m. – 11:45 a.m.
The Ritz-Carlton Ballroom, Salon I How Functional Brain Imaging Can Help Speed Drug Development and Clinical Trials

Noon – 2:00 p.m.
The Ritz-Carlton Ballroom, Salon II Special Interest Topics and Luncheon

2:15 p.m. – 6:00 p.m.
The Ritz-Carlton Ballroom, Salon I Pipeline Session

SATURDAY, FEBRUARY 25, 2012

8:00 a.m. – 12:30 p.m.
The Ballroom Foyer Registration
(Continental Breakfast 8:45 a.m. – 9:15 a.m.)

8:30 a.m. – 9:00 a.m.
The Ritz-Carlton Ballroom, Salon I Annual Business Meeting
All members are welcome!

9:00 a.m. – 12:15 p.m.
The Ritz-Carlton Ballroom, Salon I Academic Investigators' Symposium:
Early Drug Development