

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON DC/ROCKVILLE
1750 ROCKVILLE PIKE, ROCKVILLE, MARYLAND

JANUARY 7 & 8, 2009

AGENDA

On January 7, the committee will discuss new drug application (NDA) 20-427, vigabatrin, Ovation Pharmaceuticals, Inc., for the proposed indication of adjunctive therapy for the treatment of refractory complex partial seizures in adults. On January 8, the committee will discuss NDA 22-006, vigabatrin, Ovation Pharmaceuticals, Inc., for the proposed indication of treatment of infantile spasms.

Day 1: Wednesday, January 7, 2009

8:00 a.m. Call to Order and Opening Remarks **Larry B. Goldstein, M.D.**
Acting Chair
Peripheral and Central Nervous System Drugs
Advisory Committee

Introduction of Committee

Conflict of Interest Statement **Diem-Kieu H. Ngo, Pharm.D., BCPS**
Designated Federal Official

8:15 a.m. FDA Introductory Remarks **Russell Katz, M.D.**
Director, Division of Neurology Products
Office of Drug Evaluation I, OND, CDER, FDA

INDUSTRY PRESENTATION

8:30 a.m. Sabril (vigabatrin) Tablets for
Refractory Complex Partial
Seizures – *Introduction* **Tim Cunniff, Pharm.D.**
VP, Global Regulatory Affairs, Pharmacovigilance,
and Clinical Quality Assurance
Ovation Pharmaceuticals, Inc.

8:35 a.m. Sabril (vigabatrin) Tablets for
Refractory Complex Partial
Seizures – *An Unmet Need for
Therapies* **R. Edward Faught, M.D.**
Professor and Vice Chair, Department of Neurology
University of Alabama School of Medicine
University of Alabama at Birmingham
Director, UAB Epilepsy Center

8:40 a.m. Sabril (vigabatrin) Tablets for
Refractory Complex Partial
Seizures – *Efficacy and General Safety* **Christopher Silber, M.D.**
VP, Clinical Affairs
Ovation Pharmaceuticals, Inc.

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON DC/ROCKVILLE
1750 ROCKVILLE PIKE, ROCKVILLE, MARYLAND

JANUARY 7 & 8, 2009

AGENDA
-CONTINUED-

- | | | |
|-------------------------|--|---|
| 8:55 a.m. | Sabril (vigabatrin) Tablets for Refractory Complex Partial Seizures – <i>Peripheral Visual Field Defect (pVFD) Consequences & Monitoring</i> | Robert C. Sergott, M.D.
Director of Neuro-Ophthalmology
Professor of Ophthalmology and Neurology
Wills Eye Institute, Thomas Jefferson University |
| 9:15 a.m. | Sabril (vigabatrin) Tablets for Refractory Complex Partial Seizures – <i>Peripheral Visual Field Defect (pVFD) Characterization</i> | Steven Sagar, M.D.
Medical Director
Ovation Pharmaceuticals, Inc. |
| 9:45 a.m. | Sabril (vigabatrin) Tablets and Powder for Oral Solution – <i>Risk Evaluation and Mitigation Strategy (REMS)</i> | Tim Cunniff, Pharm.D.
VP, Global Regulatory Affairs, Pharmacovigilance, and Clinical Quality Assurance
Ovation Pharmaceuticals, Inc. |
| 9:55 a.m. | Sabril (vigabatrin) Tablets for Refractory Complex Partial Seizures – <i>Benefit/Risk Assessment</i> | Roger J. Porter, M.D.
Adjunct Professor of Neurology
University of Pennsylvania, Philadelphia, PA
Adjunct Professor of Pharmacology
Uniformed Services University of the Health Sciences
Bethesda, MD |
| 10:00 a.m. | Clarifying Questions | |
| 10:15 a.m. | BREAK | |
| FDA PRESENTATION | | |
| 10:30 a.m. | Ophthalmic Findings in Adults | Ronald Farkas, M.D, Ph.D.
Clinical Reviewer, Division of Neurology Products
Office of Drug Evaluation I, OND, CDER, FDA |
| 11:30 a.m. | Vigabatrin – Risk Evaluation and Mitigation Strategies (REMS) | Joyce Weaver, Pharm.D., BCPS
Senior Drug Risk Management Analyst
Office of Surveillance and Epidemiology, CDER, FDA |
| 11:45 a.m. | Clarifying Questions | |

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON DC/ROCKVILLE
1750 ROCKVILLE PIKE, ROCKVILLE, MARYLAND

JANUARY 7 & 8, 2009

AGENDA
-CONTINUED-

- 12:00 p.m. **LUNCH**
- 1:00 p.m. Open Public Hearing
- 2:00 p.m. Questions/Clarifications
- 3:30 p.m. **BREAK**
- 3:45 p.m. Panel Discussion/Questions
- 5:30 p.m. **ADJOURNMENT**

Day 2: Thursday, January 8, 2009

- 7:30 a.m. Call to Order
- Larry B. Goldstein, M.D.**
Acting Chair
Peripheral and Central Nervous System Drugs
Advisory Committee

- Conflict of Interest Statement
- Diem-Kieu H. Ngo, Pharm.D., BCPS**
Designated Federal Official

INDUSTRY PRESENTATION

- 7:45 a.m. Sabril (vigabatrin) for Oral Solution
for Infantile Spasms – *Introduction*
- Tim Cunniff, Pharm.D.**
VP, Global Regulatory Affairs, Pharmacovigilance,
and Clinical Quality Assurance
Ovation Pharmaceuticals, Inc.
- 7:55 a.m. Sabril (vigabatrin) for Oral Solution
for Infantile Spasms – *Unmet Need
and Disease Background*
- W. Donald Shields, M.D.**
Professor of Neurology and Pediatrics
Mattel Children’s Hospital at UCLA
- 8:10 a.m. Sabril (vigabatrin) for Oral Solution
for Infantile Spasms – *Efficacy and
General Safety*
- Steven Sagar, M.D.**
Medical Director
Ovation Pharmaceuticals, Inc.

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON DC/ROCKVILLE
1750 ROCKVILLE PIKE, ROCKVILLE, MARYLAND

JANUARY 7 & 8, 2009

AGENDA
-CONTINUED-

- | | | |
|-------------------------|--|---|
| 8:50 a.m. | Intramyelinic Edema: Knowledge From Animal Studies | D. Reid Patterson, D.V.M., Ph.D.
Diplomate: ABT, ACVP, ACLAM
Fellow: ATS, IATP
Reid Patterson Consulting, Inc. |
| 8:55 a.m. | Sabril (vigabatrin) for Oral Solution for Infantile Spasms – <i>Clinical MRI Abnormalities</i> | James W. Wheless, M.D.
Professor and Chief,
Department of Pediatric Neurology
The University of Tennessee Health Science Center
Director, Neuroscience Institute & LeBonheur Comprehensive Epilepsy Program
LeBonheur Children’s Medical Center
Clinical Chief & Director of Pediatric Neurology
St. Jude Children’s Research Hospital, Memphis, TN |
| 9:10 a.m. | Sabril (vigabatrin) for Oral Solution for Infantile Spasms – <i>Benefit/Risk Assessment</i> | John M. Pellock, M.D.
Professor and Chairman
Division of Child Neurology
Virginia Commonwealth University |
| 9:15 a.m. | Clarifying Questions | |
| 9:30 a.m. | BREAK | |
| FDA PRESENTATION | | |
| 9:45 a.m. | Ophthalmic Findings in Pediatrics | Ronald Farkas, M.D., Ph.D.
Clinical Reviewer, Division of Neurology Products
Office of Drug Evaluation I, OND, CDER, FDA |
| 10:15 a.m. | Clinical Studies in Infantile Spasms | Philip Sheridan, M.D.
Clinical Reviewer, Division of Neurology Products,
Office of Drug Evaluation I, OND, CDER, FDA |
| 11:00 a.m. | Nonclinical Central Nervous System Pathological Findings | Larry C. Schmued, Ph.D.
Director, Neurohistochemistry Laboratory
Division of Neurotoxicity
National Center for Toxicological Research, FDA |

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON DC/ROCKVILLE
1750 ROCKVILLE PIKE, ROCKVILLE, MARYLAND

JANUARY 7 & 8, 2009

AGENDA
-CONTINUED-

- 11:30 a.m. Clarifying Questions
- 12:00 p.m. **LUNCH**
- 1:00 p.m. Open Public Hearing
- 2:00 p.m. Questions/Clarifications
- 3:00 p.m. **BREAK**
- 3:15 p.m. Panel Discussion/Questions
- 5:30 p.m. **ADJOURNMENT**