

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

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON, DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

OCTOBER 23, 2008

AGENDA

The Committee will discuss the clinical development of radionuclide imaging products for the detection of amyloid to assist in the diagnosis of Alzheimer's disease.

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| 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 | CAPT Rafel D. Rieves, M.D.
Director, Division of Medical Imaging and
Hematology Products (DMIHP), Office of Oncology
Drug Products (OODP), OND, CDER, FDA |
| FDA PRESENTATION | | |
| 8:30 a.m. | Overview of Potential Imaging Claims | Alexander Gorovets, M.D.
Medical Officer Team Leader
DMIHP, OODP, OND, CDER, FDA |
| 8:45 a.m. | Clinical Presentation, Diagnosis
and Management of Alzheimer's
Disease | Madhav Thambisetty, M.D., Ph.D.
Staff Clinician
Section of Brain Physiology and Metabolism
National Institute on Aging |
| 9:25 a.m. | Amyloid and Amyloid Deposition in
the Brain | William G. Rebeck, Ph.D.
Associate Professor
Department of Neuroscience
Georgetown University Medical Center |
| 9:45 a.m. | BREAK | |

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-CONTINUED-

INDUSTRY PRESENTATION

AVID RADIOPHARMACEUTICALS

- 10:00 a.m. Introduction/Background on ¹⁸F-AV-45 **Daniel Skovronsky, M.D., Ph.D.**
CEO, Avid Radiopharmaceuticals
- AD Biomarker Research and the
Clinical Role and Utility of Imaging
Amyloid Plaque **Christopher Clark, M.D.**
University of Pennsylvania, Department of Neurology
Medical Director, Avid Radiopharmaceuticals
- ¹⁸F-AV-45: Overview of Results
And Development to Date **Daniel Skovronsky, M.D., Ph.D.**
CEO, Avid Radiopharmaceuticals
- Selection of Reference Standard
and Avid Development Proposal **Daniel Skovronsky, M.D., Ph.D.**
CEO, Avid Radiopharmaceuticals

BAYER HEALTH CARE PHARMACEUTICALS

- 10:30 a.m. Introduction and Bayer Position **Madhu Anant, M.Sc.,RAC**
Deputy Director, Global Regulatory Affairs
Bayer Health Care Pharmaceuticals
- Clinical Utility **Kenneth Marek, M.D.**
Director, Institute of Neurodegenerative Disorders
Yale University Medical School
- Phase 3 Study Design – Standard
Of Truth **Cornelia Reininger, M.D. Ph.D.**
Director, Global Clinical Development
Bayer Health Care Pharmaceuticals
- Conclusion **Madhu Anant, M.Sc.,RAC**
Deputy Director, Global Regulatory Affairs
Bayer Health Care Pharmaceuticals

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GE HEALTHCARE

- 11:00 a.m. Product Introduction and Proposed Indication for GE-067 **David Brooks, M.D., D.Sc.**
Head of Neurology in Clinical Development, GE Healthcare
Hartnett Professor of Neurology, Imperial College London
- Clinical Utility of Amyloid Imaging **Keith A. Johnson, M.D.**
Assistant Professor of Neurology, Harvard University
Director of Molecular Imaging, Massachusetts General Hospital, Boston, MA
- Data to Support C-11 PIB as a Standard of Truth (SoT) **William Klunk, M.D., Ph.D.**
Professor of Psychiatry and Neurology
University of Pittsburgh, Pittsburgh, PA
- GE-067 Clinical Development Plan **David Brooks, M.D., D.Sc.**
Head of Neurology in Clinical Development, GE Healthcare
Hartnett Professor of Neurology, Imperial College London
- 11:30 a.m. FDA Summary and Considerations **Qi Feng, M.D., Ph.D.**
Medical Officer
DMIHP, OODP, OND, CDER, FDA
- 12:00 p.m. Clarifying Questions to Presenters
- 12:15 p.m. **LUNCH**
- 1:15 p.m. Open Public Hearing
- 2:15 p.m. Clarifying Questions to Presenters
- 2:45 p.m. Panel Discussion/Committee Questions
- 3:30 p.m. **BREAK**
- 3:45 p.m. Panel Discussion/Committee Questions, Continued
- 5:00 p.m. **ADJOURNMENT**