

Peripheral and Central Nervous System Drugs Advisory Committee

March 14, 2001
Vascular Dementia

The meeting was held at the Holiday Inn, in Gaithersburg, Maryland. Prior to the meeting, the members, consultants and guests had reviewed background material from the FDA. In order for the public to be informed, the background material was also available on the Dockets page before the meeting. There were approximately 150 persons in attendance.

Attendance:

PCNS and Consultants Present: Claudia Kawas, M.D., Acting Chair, Gerald Van Belle, Ph.D., LeRoy Penix, M.D., Howard Weiner, M.D., Michael Grundman, M.D., Jerry Wolinsky, M.D.,

PCNS Members Absent: Richard Penn, M.D., Ella Lacey, Ph.D.,

PCNS Guest Experts: Steven DeKosky, M.D., Philip Gorelick, M.D., Gustavo Roman, M.D., Ranjan Duara, M.D., Helena Chui, M.D.,

FDA Participants: Russell Katz, M.D., Ranjit Mani, M.D.

Overview of FDA's Presentation:

Russell Katz, M.D., gave an overview of the FDA questions for the meeting.

1. Can vascular dementia be clearly defined in a clinical setting?
2. Are there valid criteria for the diagnosis of vascular dementia?
3. Can vascular dementia be distinguished from Alzheimer's Disease and other causes of dementia?
4. What outcome measures are appropriate to use in clinical drug trials conducted in vascular dementia?
5. Should clinical drug trials in vascular dementia incorporate any special features in their design?

The Following speakers presented their viewpoints:

Gustavo Roman, M.D., University of Texas Health Science Center, San Antonio, Texas
Critical elements for the diagnosis of vascular dementia

Helena Chui, M.D., Department of Neurology, University of Southern California, Los Angeles, & Rancho Los Amigos National Rehabilitation Center, Downey, California
Focus on subtypes: Dementia due to subcortical ischemic vascular disease

Ranjan Duara, M.D., Wien Center for Alzheimer's Disease, Mount Sinai, Miami Beach, Florida
White matter disease in progressive dementias: Is it vascular or degenerative?

Philip Gorelick, M.D., MPH, FACP, Professor and Director, Center for Stroke Research, RUSH Medical College, Chicago, Illinois
Background and Potential Strategies for Prevention of Vascular Dementia

Public Speakers:

Ray Pratt, M.D., Senior Director, CNS and Internal Medicine, Eisai/Pfizer
Diagnostic Criteria, Proposed Outcome Measures and Experiences to Date

Andrew Satlin, M.D., Director, Clinical Research, Novartis Pharmaceuticals
Issues Related to the Development of Drugs for the Treatment of Patients with Vascular Dementia

Sean Lilienfeld, M.D., Director, Global Clinical Research Development – CNS, Janssen Research Foundation,
Overview of Design and Results in the Placebo Groups from Trial with Galantamine in the Treatment of Vascular and

Discussion

The committee did not vote on the questions. The committee and guests discussed the issues and their views are recorded in the transcript. A verbatim transcript of this meeting will be available on the FDA's Dockets Management Branch Website approximately 30 days after the meeting. The address is [HTTP://www.fda.gov/ohrms/dockets/ac/acmenu.htm](http://www.fda.gov/ohrms/dockets/ac/acmenu.htm).

I certify that I attended the March 14, 2001 meeting of the Peripheral and Central Nervous System Drugs Advisory Committee and that these minutes accurately reflect what transpired.


Sandra Titus, Ph.D. Date
Executive Secretary, PCNS


Claudia Kawas, M.D. Date
Acting Chair, PCNS

Prepared on March 14, 2001
Sandra Titus