



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 8 February 2008
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AGENDA

2ND WORKSHOP ON NEURODEGENERATIVE DISEASES: FOCUS ON DEMENTIA

11TH FEBRUARY 2008
EMEA
ROOM 2A
CANARY WHARF, LONDON

Chair: E. Abadie (CHMP) Co-Chair: B. van Zwieten-Boot (EWP)

Objective of the Meeting

A number of clinical development programmes is presently undertaken by the Industry aimed at making available new medicines for Dementia. While Alzheimer's disease (AD), Vascular Dementia and mixed forms are the most frequent conditions affecting the ageing population, other well characterised forms, like Parkinson's disease (PD) associated dementias and frontotemporal dementia, may deserve specific therapeutic approaches.

Homogeneity of the clinical sample is one of the prerequisites for the demonstration of efficacy in these clinical indications, and this workshop intends to further enrich the present debate over methodology of clinical programmes and adequateness of clinical end-points.

The CHMP Efficacy Working Party, the Scientific Advisory Group for CNS and the EMEA Scientific Secretariat are organising a workshop with a panel of European Experts actively involved in the clinical and non clinical research in dementia. The FDA/CDER will contribute to the debate on the current regulatory requirements in terms of development of new medicines for dementia.

The Workshop should allow the participants to convey their respective views and identify a common ground of enrichment between Academia, Patients, Healthcare Professionals, Industry and Regulators.

The elements originating during the discussion will not constitute a formal specific advice on a particular product or class of products. The positions expressed by the Experts or the CHMP/EWP, SAG-CNS or the EMEA during that Meeting will not be regarded as binding in relationship to any aspect of subsequent institutional work.

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MORNING SESSION:

Welcome Coffee

8.40

Welcome

EMEA

9:00 [5 min.]

Introductory Remarks & Scope

E. Abadie

9:05 [10 min.]

This includes the debate on the updated guidelines on AD and PD

B. van Zwieten-Boot

Alzheimer's Dementia (AD)

K. Broich, S. Bakchine, M. Rossor

1. Target Population

H Hampel

9:15

This includes biomarker approach to AD early detection and characterisation.

[20 min.+ Q]

2. Primary End-Points

K Broich

9:45

This focuses on the main requirements for AD new medicines.

[20 min.+ Q]

3. Update on issues relating to the use of neuroimaging in trials in AD

N Fox

10:15

Available data on neuroimaging techniques as a follow-up tool (including ADNI, PIB-PET, etc)

[20 min.+ Q]

Coffee Break

10:45 [15 min]

Vascular Dementia (VD)

C. Deguines, M Donaghy

1. Target Population

M. Kivipelto

11:00 [20min.]

This focuses on the epidemiologic approach to dementias

2. Specific End-Points

JM Orgogozo

11:20 [20 min.]

This focuses on the operational approach to vascular dementia

Questions

11:40 [10min]

Parkinson's and Frontotemporal dementias

C Sampaio, I. McKeith

3. Target Population and specific End-Points

I. McKeith

11:50 [20min.]

State-of-the-art of diagnostic criteria and opening for therapeutic needs (specific-or-not) for PD dementias

4. FTD: more than an exclusion diagnosis?

A. Padovani

12:10 [20 min.]

Canada and US groups recently drew attention to this challenging sub-group of dementias with little memory impairment and difficult-to-manage behavioural burden. A model for an integrated clinical /molecular approach?

Questions

12:30 [10min]

Lunch

12:40 [50 min]

AFTERNOON SESSION:

Focus on development of new medicines for Dementia

B. van Zwieten-Boot, K. Broich

1. The challenge of new developments for dementias : the FDA point of view

includes 2-3 questions

R. Katz

1:30pm [25min.]

(via
teleconference)

2. Guidelines on dementias : the challenge of disease-modifiers development

includes 2-3 questions

C. Sampaio

2:00pm [25min.]

3. Received Comments to the published guidelines

S. Del Signore

2:30pm [20min.]

As a synthetic review

Coffee Break

2:50 pm [20min]

The AFTERNOON SESSION CONTINUES:

4. General discussion with the Stakeholders

This will allow the participants to bring up their views in terms of innovative approaches (use of) and CT implementation (feasibility)

**B. van Zwieten-
Boot**

3:10pm [60min.]

5. Concluding Remarks and Future Actions

E. Abadie

4:10 pm [20 min.]

Workshop ends!

4:30 pm

Please refer to List of Speakers below

LIST OF CHAIRS AND SPEAKERS
2nd WORKSHOP ON NEURODEGENERATIVE DISEASES
FOCUS ON DEMENTIA
11th February, 2008

(in order of speaking)

<i>Name</i>	<i>Affiliation</i>
Dr Eric Abadie	Chairman of Committee for Medicinal Products for Human Use (CHMP) Agence Française de Sécurité Sanitaire des Produits de Santé, France
Dr Barbara van Zwieten-Boot	Chairman of Efficacy Working Party (EWP) CHMP member, College ter Beoordeling van Geneesmiddelen Bureau Diergeneesmiddelen, the Netherlands
Dr Karl Broich	CHMP member, Bundesinstitut für Arzneimittel und Medizinprodukte, Germany
Prof Serge Bakchine	Centre Hospitalier Universitaire Maison Blanche, France
Prof Martin Rossor	ENFS, UK
Prof Harald Hampel	Trinity College, Dublin
Prof Nick Fox	Dementia Research Centre, UCL, UK
Dr Catherine Deguines	Agence Française de Sécurité Sanitaire des Produits de Santé, France
Prof Michael Donaghy	Oxford Radcliffe Hospital, UK
Prof Miia Kivipelto	Ageing Research Centre, Karolinska Institutet, Sweden
Prof Jean-Marc Orgogozo	University Hospital Pellegrin, France
Prof Cristina Sampaio	CHMP member, Autoridade Nacional do Medicamento e Produtos de Saúde, INFARMED, Portugal
Prof Ian G McKeith	Institute for Ageing and Health, University of Newcastle upon Tyne, UK
Prof Alessandro Padovani	Università degli Studi di Brescia, UNIBS, Italy
Dr Russell G Katz	Food and Drug Administration (FDA), USA
Dr Susanna Del Signore	European Medicines Agency (EMA), UK