European Medicines Agency
Evaluation of Medicines for Human Use

London, 28 September 2006
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AGENDA

SLOWING THE PROGRESSION OF NEURODEGENERATIVE DISEASES: MEDICINAL PRODUCTS (MP) CLINICAL DEVELOPMENT

OCTOBER 2ND 2006
EMEA
ROOM 4A
CANARY WHARF, LONDON

Chairperson: B. van Zwieten-Boot (EWP)

Objective of the Meeting

An increasing number of clinical development programmes is presently undertaken by the Industry aimed at making available new medicines, which may interfere with the mechanisms of disease underlying the neuronal loss. These drugs will respond to the currently unmet therapeutic need of delaying the clinical progression of Alzheimer's disease (AD), Parkinson's disease (PD) as well as Amyotrophic Lateral Sclerosis (ALS).

In the meantime, a rich debate is in progress within the scientific community concerning the methodology of clinical trials, the adequateness of clinical end-points, the correct use of surrogate end-points, including neuroimaging techniques and biomarkers, as well as the respective applicability of these recent approaches.

The CHMP Efficacy Working Party, the Scientific Advisory Group for CNS and the EMEA Scientific Secretariat would like to contribute to the ongoing debate. In this view, they intend to organise a workshop with a panel of European Experts actively involved in the clinical research of disease modifiers for neurodegenerative diseases.

The Workshop should allow the participants to convey their respective views and identify a common ground of enrichment between researchers and regulators.

The contribution of industries that are actually pursuing and implementing this kind of clinical development and have already contacted the Agency for advice, is also envisaged. 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	**EMEA**
Introductory Remarks & Scope	**B. van Zwieten- Boot**
Amyotrophic Lateral Sclerosis (ALS)	**E. Abadie**
1. Study Design, Target Population & Clinical End-Points	**N. Leigh (UK)**
2. Panel discussion on ALS	

Discussants:
- **J. Wokke (NL)**
- **M. Donaghy (UK)**

Parkinson's disease (PD)

1. Target Population & selected Clinical End-Points	**W. Poewe (AU)**
2. Study Design & Surrogate End Points/Biomarkers	**O. Rascol (FR)**
3. Ongoing Clinical Development Programmes from the Industry & Questions	**C. Sampaio**
4. Panel discussion on PD	**A. J. Lees (UK)**

Discussants:
- **A. Lees (UK)**
- **C. Barone (IT)**
- **N. B. Mercuri (IT)**
- **S. Day (UK)**

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AFTERNOON SESSION:

Alzheimer's disease (AD)

1.	**Ongoing Clinical Development Programmes from the Industry & Questions**	**K. Broich (DE)**
2.	**Target Populations & selected Clinical End-Points**	**J.M. Orgogozo (FR)**
3.	**Surrogate End Points/Biomarkers**	**F. Jessen (DE)**
4.	**Neuroimaging 1**	**P. Scheltens (NL)**
5.	**Neuroimaging 2**	**Nordberg (SWE)**
6.	**Panel discussion on AD**	**S. Bakchine (FR)**

Discussants:

- **S. Bakchine (FR)**
- **J. P. Lepine (FR)**
- **N. Fox (UK)**
- **P. Jelle Visser (NL)**
- **C. Gispen (NL)**
- **S. Day (UK)**

	Review of previous sessions	**M. Donaghy**
1.	**General Discussion and Summaries from Panels**	**E. Abadie** **C. Sampaio** **K. Broich**
2.	**Concluding Remarks and Future Actions**	**B. van Zwieten- Boot**