EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 October 2013
EMA/263897/2013
Scientific and Regulatory Management Department

Workshop on multiple sclerosis

Final programme

17 October 2013
European Medicines Agency, London, United Kingdom

Room 2A

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Objective of the workshop

In response to the considerable interest created by the on-going revision of the current 'Guideline on clinical investigation of medicinal products for the treatment of multiple sclerosis' (MS guideline) (EMA/CHMP/771815/2011, Rev 2), the European Medicines Agency (EMA) has decided to provide an opportunity for the different stakeholders to come together and discuss the key scientific issues in the field. The main goal of the workshop is to make sure that in the revision of the MS guideline, the EMA can take into consideration the most up-to-date scientific developments in multiple sclerosis, as well as the positions of the experts in the field on the main topics in the guideline.

Programme overview

Sessions

Session 1 New outcome measures in multiple sclerosis.

Session 2 Placebo in multiple-sclerosis trials.

Session 3 Patient-reported outcomes, biomarkers and novel methodologies, and their role in the development of new multiple-sclerosis drugs.

Session 4 The population in multiple sclerosis and the staggered 'two-step approach'.

List of panellists and speakers

Tomas Salmonson	Chair of the Committee for Medicinal Products for Human Use (CHMP)
Karl Broich	Chair of the Central Nervous System Working party (CNSWP)
Robert Hemmings	Chair of the Scientific Advice Working Party (SAWP)
André Elferink	Rapporteur for the 'Guideline for the clinical investigation of medicinal products for the treatment of multiple sclerosis'
Manuel Haas	Head of CNS Office, Scientific and Regulatory Management Department, EMA
Pavel Balabanov	CNS Office, Scientific and Regulatory Management Department, EMA
Bernard Uitdehaag	University Medical Centre, Amsterdam
Bernd Kieseier	Department of Neurology, Heinrich-Heine University, Düsseldorf
Celia Oreja-Guevara	Multiple Sclerosis Unit, University Hospital San Carlos, Madrid
Diego Cadavid	Clinical Development Group, Biogen Idec, Cambridge, MA, USA
Frank Dahlke	Global Head Medical Affairs, Gilenya at Novartis
Gavin Giovannoni	Chair of Neurology, Blizard Institute, Barts and The London School of Medicine and Dentistry
George Ebers	University of Oxford and Oxford University Hospitals Trust
Gilmore O'Neill	Neurology Clinical Development Group, Biogen Idec, Cambridge, MA, USA
Gordon Francis	Vice president, Novartis AG
Hideki Garren	F.Hoffmann- la Roche Ltd., Product Development Neuroscience
Jeremy Chataway	Consultant Neurologist, National Hospital for Neurology and Neurosurgery, UK
Jeremy Hobart	Consultant Neurologist, Peninsula College of Medicine and Dentistry, Plymouth, UK
Klaus Schmierer	Blizard Institute, Barts and The London School of Medicine, UK
Luca Massacesi	University of Florence, Italy, member of SAG-Neurology
Maria Pia Sormani	Department of Health Sciences, University of Genoa, Italy

Michael Panzara	Group VP, Therapeutic Area Head for MS and Neurology, Genzyme, a Sanofi Company
Peter Chin	Global Program Medical Director, Novartis
Volker Knappertz	Head of Global Clinical Development, Multiple Sclerosis, Teva Pharmaceuticals R&D

Programme details

Thursday, 17 October 2013

8:00–8:30 Registration

Go to reception on the ground floor to register and receive your badge. Then join delegates in room 2A.

8:30–8:45 Welcome and opening

Opening remarks

Tomas Salmonson

CHMP chair

Session 1: New outcome measures in multiple sclerosis

Chaired by: Tomas Salmonson

8:45–9:05 Critical review of outcomes used in MS clinical trials

George Ebers

9:05–9:25 Disability assessment: can we combine responsiveness and clinical relevance?

Bernard Uitdehaag, MSOAC

9:25–9:40 Questions and discussion

9:40–10:00 The new outcome measures in MS: Possible better ways to assess disability that overcome limitations of the EDSS

Gilmore O'Neill, BiogenIdec (EFPIA)

10:00–10:20 Approaches to advancing patient-focussed outcomes assessment in clinical trials of MS

Jeremy Hobart, MS Society

10:20–10:35 Questions and discussion

10:35–10:55 New perception of disability — including cognition, fatigue, pain and other impairments related to MS

Diego Cadavid, BiogenIdec (EFPIA)

10:55–11:15 Cognition and fatigue as major determinants of disability

Bernd Kieseier

11:15–11:30 Questions and discussion

Session 2: Placebo in multiple-sclerosis trials

Chaired by: Robert Hemmings

11:30–11:50 Issues regarding use of placebo in MS drug trials

Peter Chin, Novartis

11:50–12:10	***Design strategies to minimise the use of placebo in MS clinical trials*** **Maria Pia Sormani, MSOAC**
12:10–12:30	***How to evaluate medications in MS when placebo-controlled RCTs are not feasible*** **Luca Massacesi**
12:30–12:50	***Questions and discussion***
12:50–13:40	**Lunch**

Session 3: Patient-reported outcomes, biomarkers and novel methodologies, and their role in the development of new multiple-sclerosis drugs

Chaired by: Robert Hemmings

13:40–14:00	***Patient-reported outcomes, biomarkers and novel methodologies, and their role in the development of new treatments for MS*** **Frank Dahlke, Novartis (EFPIA)**
14:00–14:20	***Optical coherence tomography: A role in monitoring multiple sclerosis*** **Celia Oreja-Guevara**
14.20–14:40	***Multi-arm trials with repurposed drugs in progressive MS*** **Jeremy Chataway, MS Society**
14:40–15:00	***Questions and discussion***
15:00–15:20	**Coffee break**

Session 4: The population in multiple sclerosis and the staggered 'two-step approach'

Chaired by: Karl Broich

15.20–15:40	***Assessing benefit-risk profile of novel immunomodulatory drugs with significant efficacy but with potential risks. What data should be presented at marketing-authorisation application?*** **Michael Panzara, Sanofi (EFPIA)**
15:40–16:00	***The proposed 'two-step approach' for MS treatments with a significant effect on immunity*** **Hideki Garren, Roche (EFPIA)**
16:00–16:15	***Questions and discussion***
16:15–16:35	***Current treatment guidelines for relapsing MS and the 'two-step approach' for disease-modifying therapy*** **Klaus Schmierer**
16:35–16:55	***The staggered 'two-step approach' for treatments with 'profound' effect on immunity*** **Gavin Giovannoni, European Multiple Sclerosis Platform (EMSP)**
16:55–17:10	***Questions and discussion***

17:10–17:30 ***Changing population in MS studies & concept of insufficient treatment response***

Gordon Francis, Novartis (EFPIA)

17:30–17:50 ***Clinical-development issues in progressive MS***

Volker Knappertz, Teva

17:50–18:05 ***Questions and discussion***

18:05–18:20 ***Closing remarks***

Karl Broich, CNS Working Party chair

Practical information

Venue

The European Medicines Agency can be reached by:

- Docklands Light Railway (DLR)
  The Agency is a short walk from either Westferry station or Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton stations.
- Underground
  The nearest stop for Westferry Circus is Canary Wharf station on the Jubilee Line.
- Bus
  Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.
- Boat
  River services run between Embankment, London Bridge and Canary Wharf throughout the day.
- From London City Airport
  Take a taxi to Westferry Circus or alternatively catch the DLR, which goes to Westferry station.

Map

Entering the building

The Agency operates a stringent security policy. Upon arrival at ground-floor reception, you will be provided with a security pass that will allow you to make your way to meeting room 2A on the 2nd floor. Tea and coffee will be available on your arrival in the 2nd-floor foyer.

Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

We strongly advise you to arrive sufficiently early before the start of the workshop (i.e. around 07:45), to allow enough time for registration and settling down. The registration will take place on the ground floor.

Catering

The Agency has a restaurant and a deli bar that offer a variety of food and drinks during the day. They both operate a cashless payment system. No cash or credit/debit cards are accepted.

You will be able to purchase a visitor card either from a dedicated person or from visitor card terminals which are located in the 1st-floor reception area and 3rd-floor restaurant. The terminals accept both GBP and EUR. The terminals issue a card with the balance of cash received less a £3 deposit for the card (i.e. if £10 is put into the machine, you will receive a card with £7 that can be spent in the restaurant and deli bar. The £3 will be refunded when the card is returned.)

At the end of your visit, simply reinsert the card in one of the visitor card terminals and the deposit plus any account balance will be refunded. If visiting the Agency frequently, visitors may wish to retain the card for future use.

Please note that the machine refunds in GBP coins only. For this reason, we encourage you to retain the card for future use or not to load it with more than £20.

Laptop computers

For those of you travelling from the continent and wishing to use your laptop, may we remind you to bring with you an appropriate UK power adapter.

Media disclaimer

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on European Union. The Agency herewith informs attendees that this particular meeting will be recorded and broadcast.

By attending this meeting you consent to any recording or broadcast.

Conference venue and secretariat

European Medicines Agency
7 Westferry Circus, Canary Wharf
London E14 4HB, United Kingdom
Telephone +44 (0)20 7523 7123
E-mail pavel.balabanov@ema.europa.eu, petra.slade@ema.europa.eu
Website www.ema.europa.eu