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An open-label follow-on study to assess the ongoing safety of MBP8298 in subjects with secondary progressive multiple sclerosis

Submission date 22/03/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 18/05/2007	**Overall study status** Stopped	
Last Edited 13/11/2013	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MBP8298-SP-02

Study information

Scientific Title

Study objectives
Safety assessment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by Health Canada on 15/11/2006. Individual site approvals in Canada are ongoing, with one site currently approved and enrolling patients. Regulatory submission for the UK is pending as of 22/03/2007. All other country submissions including those for Sweden, Finland, Netherlands, Denmark, Spain, Latvia, Germany, and Estonia will occur between October 2007 and October 2008.

Study design
Open-label extension study

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Secondary Progressive Multiple Sclerosis

Interventions
All participants will receive 500 mg of MBP8298 intravenously once every 6 months until the termination of the study.

As of 12/08/2009 this record has been updated to include the stopped status; this trial was terminated easrly by the sponsor. The initial anticipated end date of this trial was 27/02/2011.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

An independent pharmacovigilance group will provide safety oversight through an ongoing and regular review of serious adverse events and aggregate laboratory alert values from all subjects to identify any potential new safety data trends. The group will confer at least quarterly with the medical monitor and will notify the sponsor within 24 hours of the observance of any potential new safety findings.

The following evaluations will be made for safety assessment each time the participant comes for an injection of study drug:
1. Evaluation of adverse events
2. Laboratory results
3. Electrocardiogram (ECG) results
4. Vital signs
5. Physical examinations

Secondary outcome measures
1. Expanded Disability Status Scale (EDSS) change, measured once every 6 months (prior to each dose)
2. Quality of life, measured once every 6 months (prior to each dose) by Multiple Sclerosis Quality of Life-54 (MSQoL-54). In countries where this tool has not been translated into the local language, the Short Form-36 is used.
3. Relapse rates (each confirmed relapse will be recorded)

Brain magnetic resonance imaging (MRI) scans will be carried out on an annual basis to assess the effects of MBP8298:
4. Activity analysis (T2 lesions, gadolinium enhancing lesions)
5. Lesion burden (T2 burden of disease, chronic T1 black holes)
6. Atrophy (brain)

Overall study start date
27/02/2007

Completion date
27/07/2009

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Completion of treatment and all required evaluations of MBP8298-SP-01(ISRCTN record of this trial at http://www.controlled-trials.com/ISRCTN98373474)
2. Subject must be able and willing to give meaningful, written informed consent prior to participation in the trial, in accordance with regulatory requirements
3. Subjects must be reliable, compliant, and agree to cooperate with all trial evaluations in the investigators opinion

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
Up to 600

Key exclusion criteria
1. Pregnancy or desire to become pregnant
2. Use of any concomitant disease modifying therapy for Multiple Sclerosis (MS)

Date of first enrolment
27/02/2007

Date of final enrolment
27/07/2009

Locations

Countries of recruitment
Canada

Denmark

Estonia

Finland

Germany

Latvia

Netherlands

Spain

Sweden

United Kingdom

Study participating centre
6030-88 Street
Edmonton
Canada
T6E 6G4

Sponsor information

Organisation
BioMS Medical (Canada)

Sponsor details
6030-88 Street
Edmonton
Canada
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Sponsor type
Industry

Website
http://biomsmedical.com

ROR
https://ror.org/03fvjvp95

Funder(s)

Funder type
Industry

Funder Name
BioMS Medical (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration