

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

<b>Submission date</b> 22/03/2007	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/05/2007	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/11/2013	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Ms Roxanne Morton

### Contact details

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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 early 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  
T6E 6G4

## 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