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## **MEDICAL UPDATE MEMO DECEMBER 21, 2004**

### **INITIAL ENROLLMENT BEGINS FOR CLINICAL TRIAL TESTING THERAPY FOR SECONDARY- PROGRESSIVE MS**

#### **SUMMARY**

BioMS Medical Corp. has announced that the first participants are being enrolled in a large, multi-centre, placebo controlled international clinical trial to test the potential benefit of a synthetic peptide called MBP8298 as a treatment for secondary-progressive MS. The first centre to enrol participants is the MS Clinic at St. Michael's Hospital in Toronto. Other participating research centres will be announced as they begin to accept study participants. The company will update information regularly at its website: [www.biomsmedical.com](http://www.biomsmedical.com) The criteria for participation are listed below. MBP8298 is a synthetic segment of myelin basic protein which has been developed by Dr. Kenneth Warren and Ingrid Catz at the University of Alberta. A small study of 32 people found there was a trend to less worsening in the treated group compared to those who did not receive the active treatment.

#### **DETAILS**

BioMS Medical Corp. has announced that the first participants are being enrolled in a large, multi-centre, placebo controlled international clinical trial to test the potential benefit of MBP8298 as a treatment for secondary-progressive MS.

#### **Clinical trial outcome measures**

The clinical trial will involve 553 people with confirmed secondary-progressive MS and take place at research centres in Canada and Great Britain. Participants will receive either MBP8298 or inactive placebo intravenously (into a vein) every six months for a period of two years. The primary clinical endpoint for the study is the statistically and clinically significant increase in the time that it takes the disease to worsen as measured by the Expanded Disability Status Scale (EDSS). Participants will be assessed in two groups: those with the immune response genes HLA-DR2 or HLA-DR4 and those without. Up to 75 percent of people have these two immune response genes. The study will also evaluate the safety of MBP8298 in people with secondary-progressive MS.

The first research centre to enrol participants is the MS Clinic at St. Michael's Hospital. Other research centres will begin enrolling participants in the near future. It is anticipated most centres will draw on their own patient lists for participants. The telephone number for the St. Michael's Hospital MS clinical trial coordinator is 416 864-5834. The company will also update information regularly at its website: [www.biomsmedical.com](http://www.biomsmedical.com)

### **Clinical trial criteria**

Each research centre will determine participation in the study based on key inclusion criteria:

- Age between 18 and 65 years old
- Diagnosis of secondary-progressive multiple sclerosis by a neurologist
- Diagnosis of multiple sclerosis for at least three years
- Having an Expanded Disability Status Scale (EDSS) score between 3.5 (moderate disability in one functional motor system-cerebellar/pyramidal; fully ambulatory) and 6.5 (constant bilateral assistance required to walk 10m without resting, moderate disability in two functional systems)
- Clinical evidence of worsening of MS within the last three years
- Must not be allergic to glatiramer acetate (Copaxone®) or gadolinium
- Must not have ever taken cladribine, monoclonal antibodies
- Must never have been treated with irradiation for MS
- Must not be infected with the AIDS virus, or with Hepatitis B or C
- Must not be pregnant or breast-feeding
- Must not have had cancer before (with the exception of basal cell carcinoma)
- Willing, able, reliable and agree to cooperate with all trial evaluations

### **Background**

Kenneth Warren, M.D., director of the MS Clinic in Edmonton, and Ingrid Catz, M.Sc., researcher at the University of Alberta, have developed a synthetic segment of myelin basic protein called MBP8298. The researchers have been involved in the development of MBP8298 for more than 20 years. The investigators have given the product to approximately 100 people over the past 10 years in both Phase I and Phase II clinical studies. They report that of 41 people with progressive MS, 61% went into remission as measured by antibody levels in spinal fluid. The investigators report there are no clinically relevant side effects in those who have been given MBP8298 to date.

A four-year Phase II study involved 32 people with either primary-progressive or secondary-progressive MS. Sixteen participants were given 500 mg of MBP8298 intravenously every six months for two years and the remaining 16 received a sham procedure. This was followed by an open label phase in which both groups received MBP8298. The primary outcome was clinical progression (worsening) as measured by changes in the standard Expanded Disability Status Scale (EDSS). Five out of the 16 participants in the treated group became worse as measured by EDSS compared to nine out of 16 participants in the placebo group; however, because of the small size of the study group, these findings did not reach statistical significance. Using two secondary outcomes (22-metre timed walk and foot taps) there was a trend for participants in the treated group to score better than placebo although this difference did not reach statistical significance.

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