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RESEARCH/CLINICAL UPDATE

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MS TRIAL ALERT:

Enrollment Begins for Study of MBP8298 in Secondary-Progressive MS

Summary: Enrollment has begun for a study testing the safety and effectiveness of the experimental drug MBP8298 (BioMS Medical Corp.) in 510 people with secondary-progressive multiple sclerosis. Up to 60 sites nationwide will be enrolling patients by September. This drug is administered intravenously (into the vein) every 6 months. People with secondary-progressive MS experience an initial period of relapsing-remitting MS, followed by a steadily worsening disease course with or without occasional flare-ups, minor recoveries (remissions), or plateaus. This phase III study is also known as MAESTRO-03, and the primary investigator is Dr. Clyde Markowitz (University of Pennsylvania, Philadelphia).

Rationale: Multiple sclerosis occurs when the immune system mistakenly attacks nerve fiber-insulating myelin and other brain and spinal cord tissues. MBP8298, a synthetic fragment of myelin basic protein (MBP, a component of myelin), reduces the production of spinal fluid antibodies that react against MBP. In an earlier study, investigators administered 500 mg of either MBP8298 or inactive placebo to 32 people with secondary- or primary-progressive MS. A statistically significant delay in clinical progression was noted in patients with certain genetically determined "HLA" types. (HLA is a molecule located on body cells that helps the immune system recognize and attack both foreign invaders and, in the case of autoimmune diseases, the body's own tissues. Some HLA types have been linked to increased susceptibility to MS.)

In that study, the subgroup of patients with HLA types DR2 and/or DR4 experienced a delay in worsening of disease (those on placebo experienced clinical progression of MS at an average of 18 months, while those on active treatment experienced progression at an average of 78

months). Based on these results, BioMS Medical is now conducting several phase II/III studies of MBP8298 in people with MS who are positive for HLA DR2 and/or DR4.

Eligibility and Details: To enroll in this phase III study, people must be 18-65 years of age, with a documented history of secondary-progressive MS. Only people who are positive for the HLA DR2 and/or DR4 genes can participate; a blood test will be taken to determine HLA status. Participants must have had no relapse in the 3 months before the study.

Participants will be randomly assigned to receive either 500 mg of MBP8298 or inactive placebo intravenously every six months for two years. The primary goal of the study is to determine the effectiveness of MBP8298 as measured by the EDSS, a widely used rating system of clinical status. Secondary objectives are to assess the drug's effects on disease activity observed on MRI (magnetic resonance imaging scans), relapse rates, quality of life and fatigue.

Contact: For information on sites that are currently enrolling, please consult the study's listing on [clinicaltrials.gov](http://www.clinicaltrials.gov) at <http://www.clinicaltrials.gov/ct/show/NCT00468611?order=1>. Sites will be located in the following states:

Arizona	New Jersey
Arkansas	New York
California	Nevada
Colorado	North Carolina
Florida	Ohio
Georgia	Oregon
Illinois	Pennsylvania
Kentucky	Rhode Island
Maryland	Tennessee
Massachusetts	Texas
New Mexico	Vermont
Michigan	Virginia
Mississippi	Washington
Missouri	West Virginia
Montana	

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