



**National Multiple Sclerosis Society**  
733 Third Avenue  
New York, New York 10017-3288  
Tel +1 212.986.3240  
Fax +1 212.986.7981  
E-mail [nat@nmss.org](mailto:nat@nmss.org)  
[nationalmssociety.org](http://nationalmssociety.org)

## RESEARCH/CLINICAL UPDATE

<b>Keyword:</b>	BHT-3009
<b>Section:</b>	TREATMENTS, INVESTIGATIONAL

**August 17, 2007**

### **Results Published on BHT-3009, Experimental DNA Vaccine Treatment for MS**

An early-phase study of BHT-3009 (Bayhill Therapeutics), both alone and in combination with Lipitor<sup>®</sup> (atorvastatin, Pfizer, Inc.) found the drug to be safe and to induce a beneficial immune response in relapsing-remitting\* or secondary-progressive MS\*\*. BHT-3009 is a vaccine containing genetic material that instructs cells to produce myelin basic protein (MBP), a component of myelin, an immune target in MS. Lipitor is a cholesterol-lowering drug under study for its effects on immune function in MS. Amit Bar-Or, MD (Montreal Neurological Institute) and colleagues published their findings in the *Archives of Neurology* (2007;64:[early online publication](#), August 13). Results of the study, funded by Bayhill Therapeutics, were originally reported at the Annual Meeting of the American Academy of Neurology in 2006.

**Details:** Investigators randomly assigned 30 people with relapsing-remitting or secondary-progressive MS to either receive BHT-3009 (intramuscular injections in weeks 1, 3, 5, 9) with or without Lipitor (80 mg per day, oral capsules) or inactive placebo alone for 13 weeks. Those on placebo alone were later switched to BHT-3009 with or without Lipitor. Immune changes observed in the treatment groups included a decrease in attacking T cells, and in immune proteins targeting MBP. There was a reduction in tissue damage observed on imaging scans in the treatment groups compared with placebo, but the difference was not statistically significant. Adverse events were mild to moderate, and were similar in the groups taking BHT-3009 and placebo.

The authors note that, based on these results, a one-year, placebo-controlled clinical trial of BHT-3009 alone is underway in 290 people with relapsing-remitting MS; this study has completed enrollment. Further information can be found on the [clinicaltrials.gov](http://clinicaltrials.gov/ct/show/NCT00382629) website, at <http://clinicaltrials.gov/ct/show/NCT00382629>.

-- Research and Clinical Programs Department

\*Relapsing-Remitting MS is a course of MS characterized by clearly defined flare-ups followed by partial or complete recovery periods (remissions) free of disease progression.

\*\*Secondary-Progressive MS is a course of MS characterized by 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.

Lipitor® is a registered trademark of Pfizer, Inc.