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## RESEARCH/CLINICAL UPDATE

December 14, 2007

### Great Strides Moved MS Research Forward During 2007

The year 2007 saw rapid research progress in the fields of science and medicine that impact our understanding of the unpredictable neurological disease multiple sclerosis. Thanks to its generous contributors, the National MS Society was able to invest over \$46 million this year into over 440 new and ongoing MS research projects as part of its international effort to prevent, treat and cure MS.

Significant advances have been made in both clinical and laboratory studies in MS. In addition, more than 130 clinical trials are underway around the world, and still other experimental drugs are in the pipeline. Key highlights of the year include:

#### **Treatment/Pipeline**

- Several large-scale clinical trials in different forms of MS were launched, including ones testing oral medications, and a [multi-center trial](#) of the pregnancy hormone estriol in women with early relapsing-remitting MS. A [clinical trial](#) testing the potential of a marketed drug to protect the brain and spinal cord from MS damage was also launched.
- The National MS Society [launched Fast Forward](#), a technology-transfer initiative aimed at translating promising laboratory discoveries into effective new treatments for MS. Fast Forward will identify, evaluate and partner with start-up and existing companies to develop novel therapies or repurpose existing drugs for the treatment of MS, and plans are underway to make initial investments in early 2008.
- A large-scale analysis suggests that disease-modifying drugs for MS are effective in delaying disability progression in people whose MS started with relapses. The Halifax team developed estimates of drug effectiveness based on data from 590 people with MS treated over time with the drugs. Compared to estimated rates of progression before treatment, therapy was estimated to significantly reduce progression in the EDSS over the course of the period studied in people with relapsing MS. Although this study was based on clinical observations and not on a well-controlled clinical trial, it provides much-needed evidence of the longer-term benefit of therapy.
- Researchers showed for the first time that [early treatment](#) can slow the rate at which disability progresses in individuals who have had a first event suggestive of MS but who

have not yet been diagnosed with definite MS. The study was a follow-up to the completed, two-year BENEFIT study of interferon beta-1b.

- Copaxone<sup>®</sup> (glatiramer acetate, Teva Pharmaceutical Industries) [significantly reduced the risk of developing MS](#) and delayed its development in individuals with CIS (clinically isolated syndrome, a first event suggestive of MS) enrolled in the PreCISe study. According to a company press release, the company stopped the study early, began giving all participants including those on placebo an opportunity to receive glatiramer acetate for two years, and made plans to file regulatory requests to expand the drug's labeling to include patients with CIS.
- National MS Society-supported Stanford University researchers reported that a small protein ([alpha B-crystallin](#)) normally produced by cells to protect against injury may itself be a target of the MS immune attack, and that giving the protein to mice with a similar disease countered the effect. This may open the door to a potential new therapeutic approach.
- Two groups reported on studies of rituximab – a drug that depletes immune B cells, which may play a role in the immune attack on brain and spinal cord tissues in MS – at the 2007 annual meeting of the [American Academy of Neurology](#). In both studies, active MRI-detected brain lesions were significantly reduced in people with relapsing-remitting MS on rituximab versus those on placebo. This drug is also being clinically tested in primary-progressive MS.
- The National MS Society convened an international panel to discuss the ethics of conducting [placebo-controlled trials](#) in MS, an issue of increasing concern now that there are multiple, partially effective agents available to treat relapsing forms of MS. The panel's report will be widely disseminated when published.
- At a satellite meeting to [ECTRIMS 2007](#), updates were provided on the TOUCH<sup>™</sup> prescribing program in the U.S. and TYGRIS global observation program for natalizumab. As of September 2007, approximately 17,000 people worldwide were being prescribed natalizumab or were involved in clinical trials. No new cases of PML (progressive multifocal leukoencephalopathy), a brain disease that occurred in earlier clinical trials, had been confirmed.
- A [Stem Cell Research Summit](#) convened by the National MS Society and the MS International Federation in January 2007 brought together leading stem cell and MS experts to explore the potential of all types of stem cell research for the treatment of MS and to outline research priorities to help propel research in this promising field.
- Using a new machine called an optical coherence tomography scanner, or [OCT](#), investigators from Johns Hopkins and other centers reported that thinning of the nerve fiber layer at the back of the eye echoes evidence of brain shrinkage in MS, detected with MRI scanning. The study, funded by the National MS Society's Promise: 2010 initiative on Nervous System Repair and Protection, suggests this new tool may detect global information about disease progression in the brains of people with MS and may ultimately be useful in clinical trials of strategies to repair or protect the nervous system.

## Risk Factors/Clues to the Cause

- The International MS Genetics Consortium identified two new genetic variations associated with MS and preliminary evidence for an additional eleven variations, completing the largest replicated [whole genome scan](#) (scan of all the genes in the body) for MS to date. The study, funded in part by the National MS Society, points to potential mechanisms underlying the disease and present possible new targets for designing better therapies to stop the immune attack in MS.
- Investigators in Italy and the United Kingdom reported finding traces of [Epstein-Barr virus](#) (EBV) in brain specimens from people with different forms of MS, but not in other neurological diseases. If these exciting findings are confirmed by other laboratories, they add to growing evidence of a link between EBV and MS. However, it is not yet possible to determine whether EBV actually causes MS.
- Harvard researchers supported by the National MS Society compared levels of [vitamin D](#) in serum stored from military personnel during their service, and found that those with higher levels of vitamin D were at lower risk for later developing MS. In a somewhat related report, University of Southern California researchers found that [sun exposure](#) during childhood was associated with a reduced risk of MS in a study of 79 pairs of twins in which one twin had MS. Both studies add to growing evidence that sun exposure (or the vitamin D levels, including those produced by the body in response to sun) may help protect against the development of MS.
- Italian researchers reported on a scan of the genetic material of a group of 197 people with primary-progressive MS, a course with progression from onset, experienced by about 10% of those diagnosed with MS. They selected 20 genetic variations for further study. One variation in the HLA region (immune system genes associated with MS) was more than twice as common in PP MS as in controls. They reported their findings at the 2007 European Committee for Treatment and Research in MS ([ECTRIMS](#)) meeting.
- The National MS Society's Task Force on Epidemiology of MS met to establish research priorities for epidemiologic studies that examine aspects of people who get MS for clues to its cause. A comprehensive report of their recommendations is being prepared and will be distributed to agencies – such as the NIH and the CDC – that can implement the recommended studies.

## Impacts of MS on People

- The journal *Neurology* published a supplement on [pediatric MS](#), the first of its kind, funded by the National MS Society and written by the International Pediatric MS Study Group. The nine papers on what is known about diagnosing and managing MS in children begin to provide sorely needed guidance for pediatricians and neurologists treating children with MS.
- Washington University investigators found differences in immune system responses between a group of [African Americans](#) with MS compared with Caucasians. Antibodies (IgG) in the spinal fluid were on average 29% higher in African Americans. These

findings may help explain previous research showing that clinical symptoms differed between these groups.

- A Harvard-based study of [insurance coverage](#) involving a nationwide sampling of people with MS found that many experienced financial strain related to obtaining adequate health care, including paying for medications. The study, commissioned by the National MS Society, will inform ongoing efforts to improve health insurance coverage for people with MS.

These and other leaps forward have made 2007 a momentous year in the fight against MS.

-- Research and Clinical Programs Department

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