



**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>	<b>Daclizumab</b>
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### **Small Phase 2 Study of Daclizumab Shows Benefit Alone and in Combination with Interferon**

Researchers report that daclizumab (PDL Biopharma, Inc. and Biogen Idec) alone or in combination with interferon beta reduced disease activity on MRI and improved symptoms in nine people with relapsing-remitting multiple sclerosis\*. John W. Rose, MD and colleagues (University of Utah, Salt Lake City) report their findings in the August 21 issue of *Neurology* (2007;69:785-789).

**Details:** Daclizumab is a laboratory-created monoclonal antibody that blocks the activity of interleukin-2 receptor-alpha, a key immune activator in MS. The drug is approved for use in organ transplant rejection. In a previous study, John Rose, MD, and colleagues (University of Utah, Salt Lake City) administered daclizumab alone or along with interferon beta to 19 people with relapsing-remitting or secondary-progressive MS\*. Treatment resulted in stability (nine patients) or improvement (10 patients) of disability and a significant reduction of disease activity observed on MRI scans (*Annals of Neurology* 2004 Dec;56(6):864-7). Now Dr. Rose's team has published the results of a phase 2 study.

Investigators enrolled people with MS who were taking interferon beta but continued to have relapses and active lesions (areas of myelin damage) on MRI. Daclizumab (1 mg/kg) was administered intravenously, and again two weeks later, followed by treatments every 4 weeks. Interferon beta was continued for 5.5 months, and then participants took daclizumab alone. At that point, people who continued to have active lesions were restarted on interferon therapy along with daclizumab therapy (1.5 mg/kg) every 28 days.

Nine people completed 27.5 months of daclizumab therapy; three of them had to be restarted on interferon beta at 5.5 months. Active lesions were reduced significantly during the study,

and new lesions were reduced fourfold. The number of relapses was significantly reduced and scores measuring disease activity and symptoms improved. Two patients enrolled in the study had to discontinue therapy due to, in one patient, urinary tract infection and a severe relapse that occurred when treatment began, and in another patient, to a decrease in blood platelets. Side effects in people continuing treatment included rash (2 people), fever (1 person), and swelling of the lymph nodes (1 person).

The authors note in particular that, for three participants, the drug achieved its effectiveness in combination with interferon. “Monotherapy can be effective for some patients, but others will require combination therapy for optimal disease suppression,” they write.

Larger studies of daclizumab already are underway. In a press release dated March 12, 2007, Biogen Idec, Inc. and PDL BioPharma, Inc. reported preliminary results from its ongoing double-blind, placebo-controlled trial of daclizumab in 230 people with relapsing MS who are taking interferon beta. Patients receiving daclizumab 2 mg/kg every 2 weeks showed a significant reduction in the number of new or enlarged active lesions at week 24. The results are expected to be presented formally later this year. Another phase II study in 297 people with relapsing-remitting MS is planned for this fall in Europe.

Interesting findings indirectly relating to daclizumab were recently reported from the International MS Genetics Consortium. The team’s high-powered analysis showed a highly significant association between a variant (“polymorphism”) of the gene for interleukin-2 receptor-alpha and MS.

-- 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.