National Multiple Sclerosis Society News Sheets

PROGRAMS & SERVICES

December 16, 2011	**CC:**
February, 2012 Telelearning Opportunity for Society Connection Program Volunteers	
Action Requested by February 1, 2012	

The second telelearning for fiscal year 2012 for all Society connection program volunteers (self-help group leaders, peer support and MSFriends) is scheduled for Wednesday, February 8, 2012. The topic is: ***Making Comfortable Treatment Decisions: Tips for Thinking Clearly about Benefits and Risks.***

With new treatments approved for MS and many others being promoted on the Internet and in the social media, treatment choices are becoming increasingly complex. How does one distinguish facts from wishful thinking or a sales pitch? How can people weigh potential benefits against possible risks? What if you and your doctor don't agree? What if family members have different opinions? This telelearning will offer up-to-date information about the treatment landscape and provide practical strategies for evaluating treatment options for volunteers to share with their group members and peers.

The presenter for this teletraining is Rosalind Kalb, PhD. Dr. Kalb is Vice President of the Society's Professional Resource Center, developing and providing educational materials and consultation services for healthcare professionals. As a clinical psychologist in private practice, Dr. Kalb provided individual and family therapy for people living with MS for more than 30 years.

This learning opportunity is open to all Society self-help group leaders, peer support and MSFriends volunteers.

SCHEDULE

Due to the availability of the presenter only one call is scheduled.

- Wednesday, February 8, 2012 from 1-2:00 pm ET (12 pm CT, 11 am MT, 10 am PT)

The call will be recorded for those who miss it or would like to listen again. A playback number will be provided for you to share with your volunteers. The recording and associated handout will also be available for download on the self-help group leaders' resource page on the Society's website (http://www.nationalmssociety.org/selfhelpgroupleaders.)

http://www.nationalmssociety.org/living-with-multiple-sclerosis/connection-programs/resources-and-support-for-self-help-group-leaders/index.aspx
Call participants will be invited to submit questions prior to the call. Participants will also be provided instructions on how to submit questions after the call, whether they listen to it live or the recording.

COST

There is no cost to chapters or participants for this telelearning opportunity.

REGISTRATION AND CANCELLATION INFORMATION

The registration form and marketing handout are available on SharePoint: Programs and Services>Social Connections and Support Resources>Self Help Group Materials. For registration purposes you can customize the marketing handout with your chapter contact's name, phone number and email address.

Due to numerous factors, including the need to reserve lines with the conference call company, charges for unused lines, and the distribution of call information and handouts, registration and cancellation deadlines have been established. The **registration deadline** is **Wednesday, February 1, 2012** (2 pm ET, 1pm CT, 12 pm MT, 11 am PT). Chapters needing to **cancel a registration** should do so no later than **Monday, February 6th**. Please send all registrations and change notifications to Selfhelpgroupleaderregistrations@nmss.org.

The Programs and Services Department will e-mail the training handouts to all volunteers registered on or before the registration deadline. Hard copies will be mailed to volunteers without an email address. For registrations received after the **February 1, 2012** deadline, chapters will be responsible for distributing the training-related handouts to those registrants.

Please address any registration-related questions to Heather Webb Jones in the Programs and Services Department at 303-698-6100, ext. 15176 or heather.webb.jones@nmss.org.

Topics and dates for future telelearnings will be announced in upcoming news sheets.

Additional questions or suggestions for FY 2012 telelearning topics can be directed to Kim Koch at (303) 698-6100, ext. 15158 or kimberly.koch@nmss.org.

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RESEARCH/CLINICAL UPDATE

	cc: Chapter President, Programs, Development

December 23, 2011

Study Shows Potential of Lab Test to Detect Virus Which Causes PML in People with MS – ongoing study may help identify risk for PML in people treated with natalizumab

Biogen Idec researchers have published results on a blood test that detects antibodies to the JC virus, the virus responsible for PML (a severe brain infection). PML has emerged in some people who have taken natalizumab (Tysabri,® http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/medications/natalizumab/index.aspx Biogen Idec and Elan. Read more about natalizumab and PML http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=2308.). This paper (Annals of Neurology 2011;70:742-750 http://onlinelibrary.wiley.com/doi/10.1002/ana.22606/abstract) reports that in an ongoing study of 1,096 people in the U.S. with relapsing MS being treated or considering treatment with Tysabri, 56% had evidence of JC virus antibodies. The presence of antibodies indicates that a person has at some point been infected by or exposed to the virus, which usually lies dormant. Ultimately the study may show whether detection of antibodies to JC virus can predict an individual's risk for developing PML and help guide treatment decisions.

Details: In studies of patients who have developed PML on Tysabri, all of those tested had serum antibodies prior to the onset of PML. The company has been conducting ongoing studies of its two-step laboratory test (called STRATIFY JC virus™) to determine whether the incidence of PML in Tysabri-treated patients is lower in those who do not have detectable antibodies to JC virus.

In this study, called STRATIFY-1, women had a lower prevalence of antibodies than men (53.4% versus 64.3%), and antibodies were more prevalent with older age. The false-negative rate was 2.7%, meaning that in about 3 out of 100 times, the lab test failed to detect JC virus antibodies in patients who had evidence of the virus DNA detected by a urine test.

The company is continuing to test people starting or already taking natalizumab therapy to determine whether the lab test can reliably predict a person's risk for developing PML, which may help doctors and patients make more informed treatment choices. Read more (http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=3247) about the STRATIFY study.

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RESEARCH/CLINICAL UPDATE

	cc: Chapter President, Programs, Development

December 23, 2011

MS Trial Alert:
Investigators Recruiting for Study of Ocrelizumab in Primary-Progressive MS

Summary: Investigators worldwide are recruiting 630 people with primary-progressive MS (http://www.nationalmssociety.org/about-multiple-sclerosis/progressive-ms/primary-progressive-ms/index.aspx) to study the effectiveness of intravenous ocrelizumab (Genentech) versus inactive placebo. This experimental therapy is also being tested in relapsing MS. The study is funded by F. Hoffmann-La Roche Ltd.

Rationale: Ocrelizumab is a monoclonal antibody that binds to a molecule (CD20) on the surface of select B cells and depletes them from the body. B cells are immune cells that make antibodies and conduct other functions, and play a role in the immune attack on the brain and spinal cord in MS. The drug is a humanized antibody, similar to rituximab, a human/mouse antibody to CD20 that has previously shown benefit in people with relapsing-remitting MS, and had mixed results in primary-progressive MS. In an ongoing proof-of-concept study in relapsing-remitting MS, 2 doses of ocrelizumab were tested (600 mg and 2000 mg). Both were found to significantly reduce disease activity as measured by brain MRI (magnetic resonance imaging) scans and clinical attacks (relapses) versus placebo. One person on the higher dose (2000 mg) died due to consequences of liver and kidney failure; the relation of this death to the study medication is unclear. (*The Lancet*, published online November 1, 2011 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)61649-8/abstract).

Eligibility and Details: Participants should be ages 18 to 55, with a diagnosis of primary-progressive MS. More details on the enrollment criteria are available from the contact below.

Participants are being randomly assigned to receive ocrelizumab (2 intravenous infusions of 300 mg separated by 14 days in each 24-week treatment cycle) or placebo infusion for 120

weeks. All patients will receive the steroid methylprednisolone (100 mg intravenously) 30 minutes before their infusions.

The primary outcome being measured is the time to onset of sustained disability progression (an increase in the EDSS disability scale that is sustained for at least 12 weeks). Secondary outcomes include the time to EDSS progression that is sustained for at least 24 weeks; change in walking speed; change in disease activity on MRI scans; and safety and tolerability.

Contact: To learn more about the enrollment criteria for this study, and to find out if you are eligible to participate, please call 1-888-662-6728 (U.S. only) or email genentechclinicaltrials@druginfo.com, and reference Study ID Number: WA25046.

Sites in the United States that are recruiting include the following cities:

Phoenix, Arizona
Scottsdale, Arizona
Oakland, California
Sacramento, California
San Francisco, California
Aurora, Colorado
Bradenton, Florida
Maitland, Florida
Miami, Florida
Tampa, Florida
Vero Beach, Florida
Atlanta, Georgia
Chicago, Illinois
Kansas City, Kansas
Lenexa, Kansas
Detroit, Michigan
Farmington Hills, Michigan
Minneapolis, Minnesota
St. Louis, Missouri
Teaneck, New Jersey
Albuquerque, New Mexico
Albany, New York
Mineola, New York
New York, New York
Patchogue, New York
Rochester, New York
Stony Brook, New York
Advance, North Carolina
Charlotte, North Carolina
Tualatin, Oregon
Philadelphia, Pennsylvania
Providence, Rhode Island
Dallas, Texas
Houston, Texas
Round Rock, Texas
Henrico, Virginia
Milwaukee, Wisconsin

Download a brochure that discusses issues to think about when considering enrolling in an MS clinical trial (PDF).

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RESEARCH/CLINICAL UPDATE

	cc: Chapter President, Programs, Development

December 23, 2011

Results from Trial Comparing Teriflunomide and Rebif in Relapsing MS Do Not Meet Primary Goal

A new study comparing the investigational oral teriflunomide (Sanofi-Aventis) with Rebif® (interferon beta-1a, EMD Serono and Pfizer) in relapsing multiple sclerosis did not reach its primary endpoint, announced Sanofi-Aventis and its subsidiary Genzyme in a press release dated December 20, 2011. The primary endpoint (the main question posed by the study) was "risk of failure," meaning the first occurrence of a relapse, or permanent discontinuation of the study treatment, whichever came first. There was no significant difference in the numbers of participants who experienced events defined as treatment failure among the teriflunomide and Rebif groups.

According to the press release, detailed results of the TENERE study will be presented at an upcoming medical meeting. This is the second completed of five phase III studies involving teriflunomide in multiple sclerosis. An application for marketing approval of teriflunomide was accepted for review by the U.S. Food and Drug Administration in October 2011.

Background: Multiple sclerosis occurs when the immune system attacks the brain and spinal cord. Teriflunomide is a novel oral compound that inhibits the function of specific immune cells. In the TEMSO study reported earlier this year, teriflunomide reduced the average number of MS relapses and disease activity on MRI scans significantly more than inactive placebo in 796 people with relapsing forms of MS. Read more (http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=5577) about this study.

Other phase 3 studies of teriflunomide are ongoing, including the TOWER study in 1110 people with relapsing forms of MS (teriflunomide vs. placebo); the TOPIC study in 780 people at high risk for developing MS (teriflunomide vs. placebo); and the TERACLES study in 1455 people with relapsing MS (teriflunomide vs. placebo added on to interferon beta).

The Study: For the TENERE trial, investigators worldwide recruited 324 people with relapsing MS, and randomly assigned them to receive teriflunomide 7 mg or 14 mg, once daily by mouth, or Rebif 44 mcg three times per week subcutaneously for 48 weeks. The primary endpoint was "risk of failure," meaning the first occurrence of a relapse, or permanent discontinuation of the study treatment, whichever came first. Secondary outcome measures included the average number of relapses per year, fatigue as reported by participants in the Fatigue Impact Scale, and satisfaction as reported by participants using the Treatment Satisfaction Questionnaire for Medication. Safety and tolerability were also assessed.

There was no significant difference in the numbers of participants who experienced events that constituted the definition of treatment failure among the teriflunomide and Rebif groups, according to the press release. Relapse rates did not differ significantly either. Details on other secondary endpoints were not provided.

Both treatments were safe and generally well tolerated. Participants in the teriflunomide groups experienced more nasal inflammation, diarrhea, hair thinning, and back pain. Those in the Rebif group experienced more increases in liver enzyme levels, headache, and flu-like symptoms.

Comment: These and results from additional phase III studies of teriflunomide that have been completed or are now underway should help define the short-term safety and promise of teriflunomide as a potential new therapy for relapsing MS.