



CHAPTER PRESIDENTS

October 2, 2009	CC: Financial Management
<input type="checkbox"/> <i>Do Not Post on NMSS.org</i>	
2009 Financial Management Checklist	
Action Requested/Deadline: December 31, 2009	

The 2009 Financial Management Checklist is now available and can be found on the Society's Sharepoint intranet under the Finance & Accounting topic under "Forms."

This checklist is separated into two parts:

- **Part I** covers internal controls and audit procedures. This part is to be signed off by the Chapter President and the Audit Committee chair.
- **Part II** covers compliance with the Society's financial policies. This part is to be signed off by the Chapter President and the Treasurer.

You are required to complete and sign this checklist and submit it to the home office Finance Department (to the attention of David Lee), by December 31, 2009. Although we will accept a hard copy of the signed checklist, we prefer to receive a PDF file of the signed form via e-mail.

Please note that the requirement to put the audit out to be at least once every five years (item number 95) has been waived for FY09 and FY2010 due to the anticipated switch to a calendar year-end effective January 1, 2011.

Please feel free to contact me if you have any questions regarding this matter.

From: David Lee
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CHAPTER PRESIDENTS

October 2, 2009

CC: Development

[Do Not Post on NMSS.org](#)

National Research Call on Nervous System Repair & Protection Featuring Dr. Gavin Giovannoni to be Held October 15th

What if we could actually reverse the damage that MS causes, restoring function to those who have been living with the disease for years? Recognizing that this dream could be advanced more quickly through collaborative, multidisciplinary research, the Society committed in 2005 to raise funds to support the work of four expert investigative teams focusing on nervous system repair and protection as part of the *Promise: 2010 Campaign*. These teams are making significant progress, developing non-invasive tools and models for monitoring results and paving the way for clinical testing by 2010 to restore function in people with MS.

Join us for a **special research conference call focusing on the Nervous System Repair and Protection (NSRP) Initiative, to be held Thursday, October 15th at 3:00 PM Eastern**. The 60 minute call features Dr. Gavin Giovannoni and will be moderated by Dr. Patricia O’Looney, the Society’s Vice President of Biomedical Research.

Dr. Gavin Giovannoni (Queen Mary University of London, UK) is the principal investigator of a team attempting to turn cells into vehicles that will deliver repair molecules to sites of injury in the brain, and screening molecules for their protective properties as a prelude to clinical trials.

National research calls are a great way for donors, donor prospects, staff and volunteer leaders to remain abreast of the many avenues by which the Society is advancing discovery into the cause and cure of MS and to hear directly from some of the world’s leading MS researchers about the most progressive science.

Participation in national research calls is growing, as staff has embraced spreading research knowledge to various Society supporters who are critical to increasing awareness and funding of MS research. **We hope you will identify and invite participants in each of the following groups:** major donors or prospects, major gift officers, chapter presidents, additional Society staff members, board members, significant event check writers, top event fundraisers, and research advocates. The number of donors/prospects/volunteers that you invite should be consistent with your ability to make personal contact with participants after the call as suggested below.

****ADVANCE REGISTRATION IS NO LONGER REQUIRED: Dial-in directly at 877.860.4996, Conference ID 24353962. Please share these numbers with donors, staff and volunteers who intend to participate.** If there are multiple participants dialing-in from your chapter offices, please help us manage the costs associated with the calls by calling in from one phone line.

How You Can Cultivate Supporters through National Research Calls:

Identify constituents in the groups outlined above, especially those who have expressed an interest in MS research. Anyone who can get to a phone, whether in an office, home, city or rural area is able to participate. Also consider inviting prospects to join you and others for the call at the chapter office to provide greater participation and cultivation opportunities.

We suggest extending invitations via a conversation over the phone or in person, or via email. **The dial-in information may be provided directly to the participant, as registration for the call is no longer necessary.** If you would like a template email or letter invitation, please contact Carrie Radant.

After the call, maximize this cultivation opportunity by speaking with participants about their call experience and exploring their interest in supporting research. The call will be recorded and one CD will be available to each chapter for duplication. Chapters may give the CDs to call participants, donors/prospects unable to participate and future prospects/donors and/or staff. Calls are also now available under the Research section of the national website at <http://www.nationalmssociety.org/research/research-news/ConversationswithMSResearchers/index.aspx>. The CDs and weblink will be available approximately two weeks after the call; CDs must be requested.

For additional information, an invitation template, or to request a CD recording of the call, please contact me at the number or email listed below:

Carrie Radant

National Director, Donor Development
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CHAPTER PRESIDENTS

October 2, 2009	CC:
<input type="checkbox"/> Do Not Post on NMSS.org	
Update on the 2011-2015 Strategic Response	
Action Requested/Deadline: January 31, 2009	

The National Multiple Sclerosis Society has completed the outreach phase of the 2011-2015 Strategic Response process. We received over 9,000 responses to the survey (both on-line and in-person) and received input from all key audience groups. The feedback has been compelling and we thank everyone for making this phase so successful.

We have been gathering all the feedback, summarizing responses and analyzing the data. As we enter October we will prepare a white paper with recommendations for our next Strategic Response based on the high-level data review. This paper will be presented and discussed at the Delegate Assembly meeting in early November.

We will be asking for your help during our next phase of engagement. During the months of November, December and January we ask that you include this topic in one of your board and staff meetings to capture your board's and staff's thoughts on how the outreach results should be translated into our next strategic response. Your advice and feedback – from staff and volunteer leaders – during this phase will be essential in helping to develop a shared vision and plan for the Society.

We will be providing a toolkit to enable you to present the outreach findings and capture the feedback from your board and staff. More information regarding the toolkit will be provided at a later date. We will need to receive your input by January 31st in order for it to be considered in the 1st draft of the objectives for the strategic response. There will be other opportunities in the process to capture your feedback after January.

Overall Process and Timeline

- Currently, a team is gathering all feedback, summarizing responses, analyzing data and preparing a white paper
- November 5th, the white paper is presented to the Delegate Assembly for discussion and feedback
- November – January
 - Chapters use the toolkit to discuss the strategic response at board and staff meetings

- Feedback gathered from home office staff
- February, a team will incorporate feedback and create a 1st draft of the objectives for the 2011-2015 strategic response
- March – May, feedback on 1st draft of the objectives will be solicited
- June, feedback is incorporated and the proposed 2011-2015 Strategic Response is finalized
- July, the 2011-2015 Strategic Response will be presented to a special telephone meeting of the Delegate Assembly for approval

Paul Weiss
Chief Operating Officer
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DEVELOPMENT

October 2, 2009

CC: All

[Do Not Post on NMSS.org](#)

Title: 31 Pilot Chapters Launch Golden Circle Program October 1

In the past for the Society has solicited gifts from individuals through Direct Mail – primarily targeting gifts of \$1 to \$999; and Major Giving, seeking high-end gifts of \$10,000 or more. Over the years the Society has not had a consistent strategy to identify and steward mid-level donors and create a pipeline of potential major gift donors. To fill in this missing piece in the Society’s integrated fundraising strategy, the next logical step was building a comprehensive campaign that targeted annual gifts of at least \$1,000.

We brought together chapter and home office staff from a variety of disciplines to create a unique individual giving campaign. Representatives from 14 chapters and the home office, across 6 teams (including Major Gifts, Events, Finance, IT, Direct Mail and Marketing) worked fast and furious over the last 6 months to create an entire campaign including toolkit and training. The resulting pilot program for the new Golden Circle campaign officially launches October 1, 2009.

Golden Circle is a membership based program soliciting annual gifts of \$1,000 or more from individuals. It is a comprehensive program to engage and build personal relationships with donors that result in securing resources to help people affected by MS move their lives forward through services, advocacy and research.

The Golden Circle:

- Supports the Society’s integrated fundraising strategy by establishing consistent processes that help identify, cultivate and develop meaningful giving relationships with mid-level and major gift prospects
- Establishes a consistent stream of revenue that is not currently optimized in most chapters
- Features a donor-centered, Society-branded, consistent program structure, process and timeline
- Creates a platform for identifying, cultivating and soliciting major gift prospects
- Utilizes a committee structure to engage high-level volunteers and leverage peer relationships

Pilot Program

In anticipation of a Society-wide launch of the campaign in 2011, we have set up a pilot program for 2010. Chapters in the pilot program will help test the campaign materials and make recommendations to help shape the program for the future. An open pilot was announced earlier this summer and we are pleased to announce that 31 chapters joined as pilots this year, including all of region B which will be testing this from a regional perspective.

How will business be different for us going forward?

Pilot Chapters should anticipate welcoming a new campaign at much the same level as BikeMs and WalkMS. Like our current events, throughout the year chapters have a number of activities that must be completed for a successful campaign. For the first time an individual giving campaign will receive consistent, nationwide attention similar to WalkMs and BikeMS. For participating chapters this will be a consistent year-round focus on implementing the new Golden Circle program including consistent branding, business practices and a Society-wide approach to donor moves management. Golden Circle is a national effort to provide the support necessary to move individual giving from a transaction based to a relationship based approach.

More information: Susan.Goldsmith@nmss.org

View the toolkit on SharePoint

http://intranet.nmss.org/Topics/development/Pages/Golden_Circle.aspx



HUMAN RESOURCES

October 2, 2009

CC: All

[Do Not Post on NMSS.org](#)

National MS Society Flu Season Response Plan 2009-2010

The recent and increasing media attention around the H1N1 virus (referred to commonly as the Swine Flu) has many of us wondering why this flu season is receiving so much attention. Isn't it just another type of flu?

Unlike other flu strains (seasonal flu), to which many of us have already been exposed, the H1N1 strain is one that hasn't been seen since the 70's or earlier. This means that instead of potentially having some flu immunity as with other more normal recurring varieties, the H1N1 strain is more likely to catch us without the immunity that we might normally have against other flu varieties. This is why it's important to pay particular attention to this year's flu season.

The Center for Disease Control and Prevention encourages all business and organizations to be prepared for the "Flu Season". As a result, the Society is taking proactive steps to ensure that we all take extra precautions. A formal response plan has been developed with the following key objectives:

- Educate staff and clients about ways to protect their health
- Communicate appropriate information to all constituents
- Minimize flu transmission among staff members
- Maintain business operations

To ensure that the plan is implemented effectively, each office should identify a "Flu Season Coordinator" who will work as part of a collective team. I have assigned Carolyn Hayes-Gulston, the Society's Risk Manager, as the Flu Season Coordinator team leader. Carolyn will provide leadership Society-wide to ensure we are well prepared, taking measures to prevent cases of flu as much as possible, and have the appropriate plans in place for our business operations to function throughout the flu season. Coordinators from all Society offices will be vital members of this team to facilitate the appropriate implementation of our plan.

As a first step, the Society will focus on preparedness and prevention. The following are strongly recommended across all Society offices, as well as at any meetings/events facilitated by or through Society resources:

- Vaccinations:
 - We encourage all staff to get vaccinated for seasonal influenza as soon as possible. It is important to understand that the seasonal flu is different than the H1N1 and seasonal flu vaccination does not replace the need for an H1N1 vaccination. The H1N1 vaccine is available on a priority group basis (see the CDC website www.cdc.gov/h1n1flu/vaccination/acip.htm) which provides the list of who is in the high priority group).
 - People with MS should consult their health care provider regarding flu vaccinations. There are two kinds of vaccinations available; 1) an inactive virus administered via shot, and 2) a live virus administered through inhalant. Only the inactive virus should be taken by people with MS. The live-virus vaccine can increase MS activity.
- Hand Hygiene: Every location should provide staff individual hand sanitizers as well as access to any needed public sanitizer dispensers. Also ensure that tissues are readily available to assist with coughs, sneezes, and the like.
- Awareness: Every location should have postings on information throughout your locale reminding individuals of the importance of hand washing.

As an attachment to this newsheet, a “[Frequently Asked Questions](#)” document will be included to address any anticipated staff concerns. A [complete tool kit](#) will also be available to assist all Society staff with the above, including a convenient poster promoting “hand hygiene” for in-office printing, resources for ordering hand-hygiene supplies, a position description for the Flu Season Coordinator, and documents to provide guidance and a Q&A to prepare for events/meetings (both documents can be found on SharePoint under Human Resources).

A business continuity plan is essential to any operation that is faced with a situation that may impede its business operations. To formulate the initial steps of this phase, it is essential that every office identify a “back-up” to support each position. Cross training is crucial to ensure that there is always an additional person to carry on critical functions/responsibilities in the event individuals are out sick. To enhance the plan, it is essential to identify all the things that could possibly occur and impact discontinuance of your operations—the “what ifs”. Determine appropriate procedures beforehand to respond to the issues you have identified for your location and monitor them over a period of time for effectiveness.

Routine communications will be shared to keep this important issue top of mind during what is anticipated to be a busy flu season. Should you have additional comments or questions, please contact Carolyn Hayes-Gulston at Carolyn.Hayes-Gulston@nmss.org, or 212-476-0432. Thank you. Please view the [Flu Season Toolkit and FAQ's](#).

From: Paul Weiss – Chief Operating Officer



MARKETING & DEVELOPMENT

October 2, 2009	CC: All
<input type="checkbox"/> <i>Do Not Post on NMSS.org</i>	
FY 2010: E-communications Updates	

October 2009 National MS eNews

Send date: 10/15/09 (~~10/14/09~~)

Audience: Full List

The October 2009 National MS eNews (formerly known as the Nationwide E-newsletter) will be sent on Thursday, October 15. Please note the revised send date due to the anticipated release of late-breaking MS news during the week of October 12.

Individuals with a 'no email' classification on their Altair accounts will be suppressed, along with standard Direct Marketing Program excludes/suppressions. If you would like to review the updated Direct Marketing Program excludes, please visit the new Intranet: Development → FY09_Direct_Marketing_Overview_CD_Master_Exclude_Document.

Additional notes

As we approach FY 2010, we are optimizing the FY 2010 National E-mail Program. Please visit the FY 2010 Society-wide Constituent Communications Calendar (on the new Intranet at: Marketing → Constituent_Communications_Calendar_FY10) to review the most current national e-mail send dates.

For questions about the national e-communications strategy, please contact Rich Sarko at rich.sarko@nmss.org or 303-698-6100 x15171.



PROGRAMS & SERVICES

October 2, 2009

CC: Chapter Presidents

[Do Not Post on NMSS.org](#)

Financial Assistance Program – Web Content and Materials

National Web Page Live

The home office has developed a Financial Assistance Program Web page on the national site. It was developed using core program messages, with some slight modifications appropriate for use on our site, as well as some additional opportunities for related information through use of sidebars. You can find the page at www.nationalMSSociety.org/FinancialAssistance.

There are several paths a chapter may choose when creating a chapter Web page for the Financial Assistance Program.

1. Chapters may refer to the national page to “borrow” language, style and layout ideas for a unique chapter page. Chapters may make modifications and additions of chapter-specific information as long as those changes are within the guidelines of the program:
 - The name of the program is the National MS Society Financial Assistance Program. Once referred to initially, it may also be called “the Financial Assistance Program” or “the program” as appropriate.
 - There is one, common application process.
 - The program is designed to engage people to find solutions together – not just to apply for financial support.
 - Minimum covered categories must be honored, though chapter-specific details may vary.
2. Chapters may simply link to the national page instead of, or in addition, to a chapter page that is created primarily to address chapter-specific issues (specifics on covered items, etc.). This option may take a variety of shapes but it is fine to lean on the national page to provide full program details while the chapter page focuses on local aspects. The national page is intentionally not specific about covered items since this varies by chapter.

Additional Materials

Templates for a program brochure and flyer will also be available shortly. These materials will allow chapters to customize the pieces to promote local efforts while utilizing a shared

creative approach and the core program language that will be used around the country. Stay tuned in the coming weeks; a news sheet will provide info on the location of these pieces.

Financial Assistance Program: Recap

A workgroup including representatives from some 20 chapters developed common elements for the Society's financial assistance program. The National Programs Review Committee charged the workgroup to develop a more synchronized approach across chapters because:

- There is wide variation in this program from chapter to chapter with regard to: the application process, client eligibility, covered items and services, the name of the program, category and annual caps, etc.
- These variations contribute to public perception that the Society is a coalition of many different organizations instead of one cohesive organization with a common approach to helping people meet the financial challenges of MS.
- These variations create inefficiencies in the intake and assessment process managed by the IRC.
- With the current economic downturn, chapters are experiencing more requests for assistance, so guidance will be valuable as chapters stretch limited resources.

The workgroup's proposal for the following common elements was approved by the NPRC and is being rolled out.

1. Common name ("Financial Assistance Program")
2. Overarching society-wide principles
3. Application process (including common cover letter and common application and IRC protocol)
4. Minimum covered items
5. Common marketing messages (for web page, publicity materials)

It is expected that chapters will adopt these new processes and materials beginning in FY 2010; use of these common elements will be a certification requirement in FY 2010.

Full details on the Financial Assistance Program and the core messages supporting this program can be found on the intranet under Programs and Services/Financial Assistance Resources

If you have additional questions, please contact Debra.Frankel@nmss.org about program details or Chris.Yankee@nmss.org about marketing and Web aspects.



PROGRAMS AND SERVICES

October 2, 2009	CC: Advocacy
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<u>November is National Family Caregivers Month</u>	

The National MS Society is pleased to support the National Family Caregivers Association (NFCA) in their efforts to recognize family caregivers through our endorsement and recognition of November as National Family Caregivers (NFC) Month. This is a nationally recognized time set aside every year to thank, support, educate and celebrate more than 50 million family caregivers across the country currently providing an estimated \$375 billion in "free" caregiving services. Celebrating NFC Month in your community can bring attention to your programs and raise awareness about the Society.

The National MS Society and NFCA believe that family caregivers play a vital, but often unrecognized, role in caring for loved ones. Chapters may wish to plan your own local NFC Month Celebration. Visit the National Family Caregivers Association's website at www.thefamilycaregiver.org or call 800-896-3650 to learn more about celebrating National Family Caregivers Month or click [HERE](#).

On November 12, 2009 the NFCA will be hosting a FREE tele-class/webinar, *Safe & Sound: How to Prevent Medication Mishaps*. The program is designed to teach family caregivers what they can do to minimize the chances that their loved one will experience an adverse drug reaction or event. Click [HERE](#) for the program flyer. To promote the tele-class, chapters may wish to share the flyer with self-help group leaders for distribution to their group members, post on their websites, or distribute flyers at upcoming chapter events.

From: Kimberly Koch, MPA
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PROGRAMS AND SERVICES

October 2, 2009	CC:
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November All Self- Help Group Leader Teletraining	
Action Requested by November 5, 2009	

The first of four teletrainings planned for fiscal year 2010 for all self-help group leaders is scheduled for November 12, 2009. The topic is ***Thinking Outside the Box: Incorporating Nationwide Programs into Group Meetings***. Areas of interest to be discussed during the one-hour call include:

- An overview and discussion on the Society's nationwide programs
- An overview and discussion on the *Effective Communication and Self Advocacy* tool kit
- Strategies for implementing these programs in the self-help group setting
- Q & A

This training is targeted towards all self-help group leaders, regardless of how long the person has been a leader.

The facilitators for this teletraining are Kim Koch and Renee Vandlik. Ms. Koch is Associate Vice President of Family and Support Programs with the Programs and Services Department. Ms. Vandlik is Senior Manager of State Government Relations in the Advocacy Department.

SCHEDULE

Two teletraining calls have been scheduled. Group leaders choose one of the two calls. It is the same agenda offered at two different times.

- Call 1 is Thursday, November 12, 2009 from **1-2 pm** ET (12 pm CT, 11 am MT, 10 am PT)
- Call 2 is Thursday, November 12, 2009 from **7-8 pm** ET (6 pm CT, 5 pm MT, 4 pm PT)

COST

There is not cost for this call. This teletraining is made possible through an unrestricted educational grant from Teva Neuroscience.

REGISTRATION AND CANCELLATION INFORMATION

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** for this teletraining is **Thursday, November 5th**.

Chapters needing to **cancel** a registration must do so no later than three business days before the call (**on or before Monday, November 9, 2009.**) Please send all change notifications to Julie Gibson (contact information below).

The registration form is available by clicking [here](#): or online at: Client Programs>Programs>Self Help Groups>November All SHGL Teletraining Registration Form.

Approximately 7-10 days prior to the teletraining, the Programs and Services Department will e-mail the training handouts to chapters to distribute to their leaders registered for the training.

Please address questions to Julie Gibson who manages this program as a project consultant for the Programs and Services Department. Julie can be reached at (253) 921-2027 (Pacific Time) or Julie.Gibson@nmss.org.

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

FROM: Kimberly Koch, MPA
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PROGRAMS AND SERVICES

October 2, 2009

CC:

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Upcoming Teleconference for Families with a Child or Teen with MS

Action Requested/Deadline: Registration deadline is November 15, 2009.

The New Jersey Metro chapter, in collaboration with the Network for Children and Teens with MS and their Families, is hosting an upcoming teleconference for parents with a child or teen with MS. The call will feature a presentation on navigating the Social Security system. The presenter for the teleconference is Carl Robinson. Mr. Robinson is a Public Affairs Specialist working out of the Area 5 Director's Office in Trenton, New Jersey. He has worked for Social Security for 35 years.

The teleconference is scheduled for Tuesday, November 17, 2009 from 2:00-3:00 p.m. Eastern Time. Topics to be covered during the call include:

- When to apply for Social Security
- Navigating the Social Security website
- Reviewing eligibility requirements
- Familiarizing clients on the Social Security application forms
- Answers to Frequently Asked Questions

In addition to the formal presentation, time is scheduled for Q&A.

This teleconference is **open to all family members**, parents, children and teens with MS, and siblings are invited to participate. Families may call 1-866-543-7967 to register. Please share the attached teleconference handout with families with a child/teen with MS in your chapter. The deadline for registration is November 15, 2009. The call will be taped and made available for download at a future date.

There is **no charge** for the call. The Programs and Services Department will cover the long-distance costs. Registered families will be provided with a toll-free call-in number and handouts prior to the call.

Thank you to the New Jersey Metro chapter for hosting this important teleconference. Chapters interested in hosting future collaborative nationwide teleconferences for children and teens with MS and their families are asked to contact Kim Koch for more information (contact information below).

From: Kimberly Koch, MPA
Associate Vice President, Family and Support Programs
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Click [Here](#) to download the registration form.



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RESEARCH/CLINICAL UPDATE

[Do Not Post on NMSS.org](#) | cc: Chapter Presidents, Programs & Services

September 30, 2009

Sponsor applies to FDA for approval of oral Cladribine for relapsing MS ***– approval would mean first oral disease-modifying therapy for MS***

EMD Serono has announced that it has applied to the U.S. Food and Drug Administration seeking approval to market cladribine as the first oral [disease-modifying therapy](#) for relapsing forms of MS. In a large-scale phase 3 clinical trial, cladribine tablets significantly reduced relapse rates and other disease activity in people with relapsing-remitting MS. According to company spokespersons, the FDA has not yet made a decision about whether this drug will receive a priority review, which would expedite the time the agency has to make an approval decision.

Background/Trial Results: Cladribine is a chemotherapy that kills immune T cells and B cells, both of which are thought to be involved in immune attacks in MS. Injectable cladribine is used to treat hairy cell leukemia.

The large-scale phase 3 study that formed the basis of the application was the two-year “CLARITY” study, which was financed by the sponsor. During its first year, 1,326 participants were randomly assigned to receive a low dose of cladribine (two treatment cycles per year, each cycle consisting of one tablet per day for four to five consecutive days), a high dose (four cycles) of cladribine, or inactive placebo. In the second year, both treatment groups received a low dose of cladribine.

The primary endpoint was the drug’s effect on relapse rate at two years compared with placebo. The results, announced in a press release and in subsequent medical meetings, showed that relapse rates were reduced significantly more than placebo in both treatment groups (by 58% in the low-dose group and by 55% in the high-dose group). Those on placebo had an average of 0.33 relapses per year, versus 0.14 or 0.15 for those on therapy.

Cladribine tablets also reduced disease activity detected with MRI brain scans, including reductions in the volume of brain lesions (areas of damage) and in the number of active

lesions. A greater proportion of those with no new disease activity were on active treatment (44.3% on a higher dose, 43% on a lower dose) versus those on inactive placebo (16%), and the drug also reduced the risk of disease progression by about 32% relative to placebo.

In terms of safety, 8.7% of those on cladribine experienced serious adverse events, versus 6.4% of those on placebo. There were 5 cases of different types of cancer among the 889 people who were on active therapy, and one of the main side effects experienced by those on active therapy was deficiency of white blood cells (lymphopenia), which might be expected from this type of agent and which would probably require monitoring if the drug becomes an approved therapy.

In addition to the completed CLARITY study, other ongoing studies of oral cladribine funded by EMD Serono include:

- The ONWARD study, an investigation of the safety and effectiveness of adding high or low doses of oral cladribine to interferons in a trial recruiting 260 people with relapsing forms of MS ([this study is currently recruiting participants](#)); and
- The ORACLE MS study, designed to evaluate the safety and effectiveness of oral cladribine in people who have experienced a neurological episode that puts them at risk for developing MS ([this study is currently recruiting participants](#)).

Comment: “If the FDA’s review of oral cladribine finds it to be safe and effective for people with relapsing MS, it would represent a major treatment breakthrough – hopefully the first of many successful oral therapies in the pipeline,” said John R. Richert, MD, Executive Vice President of Research and Clinical Programs at the National MS Society.

-- Research and Clinical Programs Department

Read more on the Intranet: [FAQ About Oral Cladribine](#)
http://intranet.nmss.org/Topics/cr/Pages/FAQ_About_Oral_Cladribine_Submission_to_FDA.pdf



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RESEARCH/CLINICAL UPDATE

[Do Not Post on NMSS.org](#) | cc: Chapter Presidents, Programs

September 30, 2009

Positive Results Announced from Phase 3 Trial of Fingolimod Pills in Relapsing MS

Novartis International AG announced today that oral FTY720 (fingolimod) was able to significantly reduce relapse rates and slow disability progression over two years in a large-scale, phase 3 trial involving 1,272 people with relapsing-remitting MS. According to a company press release, safety data confirmed a positive benefit-risk profile for the lower of two doses tested, and the company plans to submit applications to drug regulatory agencies for marketing approval of the potential therapy at the end of 2009.

Background: FTY720 binds to a docking site (sphingosine-1-phosphate receptor, or S1P receptor) on immune cells, including T cells and B cells, that have been implicated in causing nervous system damage in MS. The drug appears to induce immune cells to remain in lymph nodes, where they can do little harm, preventing them from migrating into the brain and spinal cord.

Positive results from an earlier phase 2 study led to several large-scale phase 3 trials. Initial positive results from the TRANSFORMS study, comparing two different doses of fingolimod with Avonex[®] (interferon beta-1a, Biogen Idec) over only one year were presented at the American Academy of Neurology meeting in spring 2009. Adverse side effects seen more often in the fingolimod treatment groups in this trial included temporary reductions in heart rate at the start of therapy, small increases in blood pressure, and a few cases of macular edema (swelling of the back of the eye). Two deaths from herpes infections occurred in the group taking the higher dose of fingolimod, and seven cases of localized skin cancer occurred in the fingolimod groups.

This Study: The FREEDOMS study involved 1,272 people who had had symptoms of relapsing-remitting MS for an average of 8.2 years at the start of the trial. The participants were randomly assigned to one of two different daily oral doses of fingolimod or inactive placebo.

The primary endpoint established for the study was the rate of relapse. Other endpoints measured included changes in disability progression, safety and disease activity detected with MRI scanning of the brain.

According to a company press release, results showed that after two years, the drug significantly reduced the annualized relapse rates by 54% (lower dose) and 60% (higher dose) compared with placebo, and reduced progression of disability by 30% (lower dose) and 32% (higher dose) over placebo. In terms of safety, the press release stated that there were no cases of macular edema or melanoma in those taking the lower dose, but further information about these potential adverse events was not provided in these initial results. There were reversible elevations of liver enzymes, lung infections, and mild elevation in blood pressure observed in those on active therapy. Three people died during the trial, one on the higher dose and two on placebo, but these deaths were not thought to be attributable to the therapy. The press release states that future development of FTY720 will focus on the lower dose.

Further details about both benefits and adverse events are expected to be released at an upcoming medical meeting in 2010. Other phase 3 clinical trials of fingolimod, including one involving people with primary progressive MS, are still under way, as are extension studies involving those who've completed trials. These should provide additional data on safety and efficacy.

Comment: "This is potentially a breakthrough study, and we look forward to seeing further details when they are available," said John R. Richert, MD, Executive Vice President of Research and Clinical Programs at the National MS Society. "Having oral therapies in the MS pipeline is real progress, and it should increase the number of people who choose to begin therapy earlier and who stay on therapy, which our experts say is the best way to combat future disease activity."

-- Research and Clinical Programs Department

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