



ADVOCACY

March 2, 2012	CC: Chapter Presidents, Programs & Services
<u>New Resource Materials on Health Insurance Exchanges for MS Activists</u>	

The Healthcare Reform Implementation Team is pleased to announce a new [‘Q and A on Health Insurance Exchanges’](#) to support MS activists’ exchange planning efforts with their state lawmakers, coalitions and interested others. The Q and A includes hyper-links to new Fact Sheets providing additional information on key concepts and related issues, and will be posted in Sharepoint under Advocacy > Healthcare Reform Resources.

These new resources will be supplemented with additional campaign materials to be highlighted at the Affordable Care Act breakfast workshop at the Public Policy Conference next week. The workshop will focus on exchange planning and legislation featuring an expert panel to provide an update on states’ progress and major challenges to exchange establishment, as well as effective messaging for various audiences based on the results of a recent public opinion poll developed by leading advocacy groups including the National MS Society. To take best advantage of the workshop and our panelist’s expertise, all GR staff and volunteers planning to attend are encouraged to review the Q and A in advance and come prepared with questions.

The panel includes Advocacy staff from the Greater Carolinas and Mid-America Chapters who will share their experiences advocating for exchanges in their states. They will address some basic questions about exchange plans as outlined below. State Activism Council members involved in the development of these materials recommend MS activists consider these same questions.

- In general, how would you describe the political climate regarding healthcare reform and exchange planning in your state?
- What is the current status of negotiations or decisions regarding exchange planning in your state?
- Who is authorized in your state to develop plans for your exchange? (advisory board, elected officials, Dept of Health, Insurance Commissioner, etc.)
- What process, if any, is or was used to involve the public in exchange planning? (field hearings, open forums, etc.), and what opportunities will the Chapter have to provide input?

- What do you see as the biggest challenge(s) to establishing effective exchange operations in your state?

The Healthcare Reform Implementation Team is available to support Chapter engagement on exchange planning and advocacy in the states, and eager to respond to your suggestions for additional materials or other information needs.

For information, contact kim.calder@nmss.org



PROGRAMS & SERVICES

March 2, 2012	CC:
<u>New Self Help Group Leader Training Registration Process Reminder</u>	

As a reminder, the Society implemented a rolling registration process for the nationwide coached training sessions for new self-help group leaders. Registrations are managed on a rolling basis, with classes beginning when a minimum number of volunteers are met; class size is limited to 5-7 volunteers. The group meets for 1½ hours/week for four weeks. The trainings are offered at no charge.

Please note: This training is for **new** self-help group leaders only. Additional learning opportunities for **all Society Connection Programs volunteers** (self-help group leaders and peer support) are offered throughout the year.

The small group, coached-based model allows for more personal attention, in-depth discussions, customization of the curriculum to the volunteers’ needs, small group activities and time for skills-based practice. A National MS Society staff member or consultant, and a veteran self-help group leader (when available) will facilitate the training calls.

The registration form is available on SharePoint at Programs and Services>Social Connections and Support Resources>Self-help Group Materials. Please direct any new leader training questions to Julie Gibson at (253) 921-2027 or Julie.Gibson@nmss.org. Julie is a project consultant for the Programs and Services Department and is providing support to this project. She will work with you and your volunteers on scheduling and related training issues.

Additional questions can be directed to Monica Aden at (303) 698-6100, ext. 15169 or monica.aden@nmss.org.



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RESEARCH/CLINICAL UPDATE

cc: Chapter President, Programs, Development

March 2, 2012

Biogen Idec Applies to FDA for Approval of BG-12 to Treat MS

Biogen Idec announced that the company has submitted a New Drug Application to the U.S. Food and Drug Administration for approval to market oral BG-12 (dimethyl fumarate) for the treatment of MS, based on positive results from several clinical trials involving people with relapsing-remitting MS.

Multiple sclerosis involves immune system attacks against brain and spinal cord tissues. Although its exact mechanism of action is not known, BG-12 is thought to inhibit immune cells and molecules and may be protective against damage to the brain and spinal cord.

BG-12 significantly reduced the proportion of people with MS who experienced relapses in the phase 3 DEFINE study of more than 1200 people with relapsing-remitting MS (<http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=4903>) and significantly reduced the average number of annual MS relapses in the phase 3 CONFIRM trial of more than 1400 people with relapsing-remitting MS (<http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=5645>). Data from the DEFINE trial were presented at the 2011 joint meeting of the European and Americas Committee for Treatment and Research in MS, and data from both trials will be presented at the Annual Meeting of the American Academy of Neurology in April 2012; abstracts can be viewed on the meeting web site (<http://www.abstracts2view.com/aan/index.php>).

“If the FDA’s review of oral BG-12 finds it to be safe and effective, it would represent an important treatment advance for people with MS,” said Aaron Miller, MD, Chief Medical Officer of the National MS Society.



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RESEARCH/CLINICAL UPDATE

cc: Chapter President, Programs, Development

March 2, 2012

Results Reported in Phase II Clinical Trial of Oral Finategrast for Relapsing MS

In a phase II trial of an oral compound called finategrast (Glaxo Smith Kline) involving 343 people with relapsing-remitting MS, the highest doses suggested benefit by reducing MRI-detected disease activity compared to placebo. Dr. David Miller (University College London Institute of Neurology) and colleagues report their findings in *Lancet Neurology* (2012; 11: 131–39, <http://preview.ncbi.nlm.nih.gov/pubmed/22226929>). Results were originally presented at the 2010 meeting of the European Committee of Treatment and Research in MS. The study was funded by GlaxoSmithKline.

Background: Multiple sclerosis involves immune system attacks on the brain and spinal cord. Similar in approach to the approved infused therapy natalizumab (Tysabri[®], Biogen Idec and Elan), oral finategrast interferes with movement of immune cells from the bloodstream into the central nervous system by blocking the molecule known as alpha 4-integrin.

The Study: Participants were randomly assigned to receive 150 mg, 600 mg, 900 mg or 1200 mg of finategrast or inactive placebo for 6 months. The primary outcome measure was the cumulative number of active (“enhancing”) new MS brain lesions (areas of tissue damage), detected with MRI scans. Secondary outcomes included relapse rate.

The two highest doses caused a significant decrease (49%) in the average rate of new lesions compared with the placebo group. No significant differences in relapse rate were observed between the finategrast groups and the placebo group. After discontinuation of the study treatment, participants were observed for 12 weeks, and disease activity in all finategrast groups returned to levels similar to the placebo group.

Urinary tract infections were reported more often in the two high dose groups, and resolved without requiring discontinuation of treatment. Some increases in liver enzymes were

observed, and these reversed after discontinuation of the study drug. No cases of PML (progressive multifocal leukoencephalopathy, a severe brain infection) occurred in this study. PML has emerged in some people who have taken natalizumab.

Comment: This study was a 6 month, phase II trial of an experimental oral therapy with similarities to natalizumab, an approved therapy given by monthly infusions. The results suggest that finategrast may reduce some signs of disease activity with no serious adverse events. However, it will be important to observe the occurrence of urinary tract infections (which did not occur in natalizumab studies) and to monitor for PML or other infections in longer, larger trials which are needed to determine finategrast's safety and effectiveness for treating MS.