



## PROGRAMS & SERVICES

April 4, 2013

CC: Chapter Presidents

### Free From Falls Evaluation of the Pilot Programs

We are pleased to announce that the evaluation of the Free From Falls pilot program has been completed. Free From Falls was developed in response to research that confirmed that people with MS are at significant risk of falling and often curtail their daily activities due to a fear of falling. The program was piloted at over 20 sites across the country with approximately 200 participants. The program was developed in collaboration with a project task force made up of volunteer healthcare professionals, staff from Southern California-Nevada and Gateway Area and the home office. The program was funded by Acorda Therapeutics, Biogen Idec, Genetech, and Teva Neuroscience.

Data was collected from participants before and directly after the program, and again 6 months later. Sara Anne Tompkins, PhD, a health services researcher evaluated the data and found the following positive results:

- Complete elimination of falls is unrealistic; however results demonstrated strong evidence of improvements in gait, balance and confidence.
- Notably, the 6-month survey found participants reported they were using the strategies they learned and showed continued improvements in confidence and behavioral fall prevention changes.
- One-on-one attention and program length that allowed time for relationship building is believed to have contributed to the success of the program.
- Proper instruction of mobility devices may be vital for improvements as research shows that people with MS who use a walking aid are at higher risk of falling.

Based on the success of the pilot project we will be seeking funding for further subsidies, and encourage you to engage clinical partners in continuing to provide this program where possible. This program consists of an 8-week curriculum with education and awareness activities focused on fall risk and prevention, as well as a weekly exercise session focused on balance and mobility. To assist with funding request submissions, a 2-page brief describing the evaluation and benefit of the program is available on SharePoint

[http://intranet.nmss.org/Topics/programs\\_services/Documents/Free from Falls Eval and Benefit.pdf](http://intranet.nmss.org/Topics/programs_services/Documents/Free_from_Falls_Eval_and_Benefit.pdf).

If you have questions, please contact Debra Frankel at [debra.frankel@nmss.org](mailto:debra.frankel@nmss.org) or Kim Koch at [kimberly.koch@nmss.org](mailto:kimberly.koch@nmss.org).



## VOLUNTEER MANAGEMENT

April 4, 2013	CC: All
<b><u>Leader in the Movement: Francesca Smith, Northern California Chapter</u></b>	

Francesca Smith wears many hats...ambassador, recruiter, role model, and **Leader in the Movement!** Her desire to have a positive impact on the MS community is inspiring others to join the MS movement!

Click [here](#) to read the story!

We invite all to share your **Leaders in the Movement** with us, and with your colleagues across the country. Do you have volunteers leading and training other volunteers? Are your volunteers empowered to use their skills and make a difference in the lives of people living with MS? Do you engage a volunteer who has unleashed their creativity to inspire others to join the movement?

Send stories to:  
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## RESEARCH/CLINICAL UPDATE

**April 9, 2013**

### **Canbex Therapeutics Raises \$ 3.2 million to Develop Treatment for Debilitating Muscle Spasms Associated with MS**

*-- Leverages Society's Fast Forward seed investment*

The National MS Society is pleased to report that Canbex Therapeutics Ltd. has completed a \$3.2 million (£2.1m) fundraising round that will enable it to finish the early development of a potential therapy for the debilitating muscle spasms known as spasticity in MS. Merck Serono Ventures led the financing for this round. This success leverages an initial investment in Canbex in 2010 by the National MS Society's Fast Forward drug development arm, validating the concept of seeding early development to speed therapies to people with MS.

Spasticity (<http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/symptoms/spasticity/index.aspx>) is a common and often painful symptom of MS that involves feelings of stiffness, tightness or sudden movements caused by a wide range of involuntary muscle spasms. Many of the current treatments for spasticity can cause significant side effects, such as muscle weakness, sedation or mood alteration that can limit their application in MS. Canbex aims to develop a new therapy called VSN16R in hopes of creating a better treatment for spasticity affecting people with all forms of MS, including progressive MS.

Canbex is a spin-out of University College London (UCL) and was founded by a leading scientific and clinical team including Dr. David Baker and Dr. David Selwood, who were later joined by Dr. Gavin Giovannoni, a practicing MS clinician who is a global leader in MS drug development and clinical research. Drs. Giovannoni and Baker were also research leaders in the Society's Promise 2010 Nervous System Repair and Protection teams.

Other participants in the current financing round included UCL Business PLC, and the Wellcome Trust, through release of funding from a 2011 Translation Award (<http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=4792>).



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## RESEARCH/CLINICAL UPDATE

**April 10, 2013**

### **Emerging Therapies, Risk Factors and Other MS Research News from American Academy of Neurology Meeting**

Over 12,000 neurologists and other researchers convened at the American Academy of Neurology's (AAN) annual meeting in San Diego in March to share progress in understanding and treating neurological diseases like MS. In most cases, studies presented are considered preliminary. Many of the results will be analyzed more thoroughly, and usually published in peer-reviewed science and medical journals. Confidence in a study's findings grows when it is repeated by others, with similar results.

Read blogs from the AAN meeting <http://blog.nationalmssociety.org/search/label/AAN>  
Read scientific summaries (abstracts) on the AAN's Website  
<http://www.abstracts2view.com/aan/>

Here are a few highlights from more than 500 MS-related presentations focusing on stopping MS, restoring function, and ending MS forever.

#### **STOPPING MS**

Many studies were presented showing continued benefit and safety of available therapies, and additional findings from therapies proceeding through the development pipeline. Other studies looked at factors that may drive MS progression and relapses, opening possibilities for stopping MS in its tracks.

#### **Emerging Therapies**

Amiloride in progressive MS: This oral blood pressure medicine was tested in a small study of 14 people with primary progressive MS because it had been shown previously to have nerve-protecting (neuroprotective) properties. Dr. Tarunya Arun of Oxford University, with colleagues in the UK and Netherlands, reported that after 3 years, treatment with amiloride resulted in a reduction of brain shrinkage associated with progressive disease, compared to what was

experienced before treatment. Further testing is getting underway in a larger study in the UK, which the National MS Society is helping to support through the UK MS Society. (Abstract S31.002)

Large trial in progressive MS: A poster presentation by Dr. David Miller of University College London and an international team suggested that good progress is being made in a large trial of Gilenya® being supported by Novartis Pharmaceuticals Corporation. The study involves more than 1000 participants with primary-progressive MS, and it's designed to determine if Gilenya can slow down MS disability compared to inactive placebo after 3 to 5 years of treatment. This is one of several large studies like this underway in progressive MS. (Abstract P07.116)

New form of existing therapy for relapsing MS: Dr. Peter Calabresi of Johns Hopkins University presented results of an international, phase 3 trial of peginterferon beta-1a in relapsing MS, a new form of Avonex® designed to stay in the body longer than the standard form. The results over one year suggest peginterferon injected under the skin every two or four weeks was effective in reducing relapse rates and also reduced the risk of progression of disability. This study is continuing into a second year. Trial sponsor Biogen Idec has announced plans to apply for regulatory approval in 2013. (Abstract S31.006)

Copaxone® in fewer doses: Dr. Omar Khan of Wayne State University, Michigan, presented results of a one-year phase 3 trial supported by Teva Pharmaceuticals suggesting that under-the-skin injections of twice the standard dose of Copaxone, taken three times per week, were effective in reducing relapses and MRI-detected disease activity, and revealed no unexpected safety issues. (Abstract S01.005)

Switching therapies: A large study in France called ENIGM tracked the impact of switching from therapy with Tysabri® to Gilenya. Among 200 people who switched after an average of 30 months on Tysabri, there was a “washout” interval of 3 to 6 months in which no therapy was given, during which 32% experienced a relapse. The researchers concluded that switching increases the likelihood of disease reactivation, and that the washout period should not be longer than 3 months. (Abstract 41.002)

More results on Tecfidera™: An evaluation of two phase 3 trials of oral dimethyl fumarate (Tecfidera, Biogen Idec), recently approved by the FDA for relapsing MS (<http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=7539>), suggested that the treatment began to take full effect against MS disease activity after 3 months' use, and the effect was sustained over the two years of the trials. (Abstract S41.005)

Extension studies: Several presentations focused on results from extension phases of completed clinical trials in relapsing-remitting MS, including the following. These often involve open-label periods where participants who were on placebo during the original trial are switched to active treatment and others participants continue on therapy and are evaluated for a period of time.

- Extension of a phase 2 study of infrequent infusions of ocrelizumab (Hoffmann-La Roche Ltd.) showed continued effectiveness at week 144 in most who continued in the study and no new serious adverse events. Ocrelizumab is in further testing for both relapsing and progressive MS. (Abstract S31.004)
- A one-year extension of a phase 3 study of oral laquinimod (Teva Pharmaceuticals) showed that the risk of disability progression was significantly reduced for those who started on active therapy in the original trial versus those who started on placebo and then switched to therapy during the extension phase. As in the original trial, the most common adverse event was elevated liver enzymes. (Abstract S41.004)
- A one-year extension of two phase 3 alemtuzumab trials (Genzyme, a Sanofi company and Bayer Healthcare Pharmaceuticals) showed there was a durable benefit against relapses and progression, often without additional IV infusions. Risks continued for adverse events including thyroid disorders and autoimmune disorders, and one person died from sepsis. Alemtuzumab is currently being evaluated by the FDA for marketing approval. (Abstract 41.001)
- A one-year extension of a phase 2 trial of daclizumab high-yield process (DAC HYP, Biogen Idec and Abbott Biotherapeutics) showed that monthly under-the-skin injections continued to reduce relapses, MRI disease activity, and disease progression. There was one death due to autoimmune hepatitis and the incidence of serious infections, skin events and liver function test abnormalities were similar to those found in the original trial. (<http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=5374>) (Abstract S01.001)

### **Exploring Disease Activity**

Can vaccinations trigger MS attacks? Dr. Mauricio Farez of Universidad del Salvador, Buenos Aires, Argentina reported on his analysis examining whether common vaccinations are linked to MS. Among his findings, he reported that vaccination against yellow fever may substantially increase the risk of MS relapse, suggesting that someone with MS who is planning a trip to a country where there's increased risk for yellow fever should discuss the risks and benefits of vaccination with an MS doctor. (Abstract S10.001)

Sugar and progression: We don't know yet why some people's MS progresses slowly and others experience rapid progression, but a small study from Drs. Wael Richeh, Jesus Lovera and colleagues at Louisiana State University gives food for thought. They asked whether blood sugar is linked to levels of MS disability, and found that people with higher levels of glucose were more likely to have higher levels of disability. This important lead needs more study to prove a role for blood sugar in MS progression. (Abstract P04.130)

Genes and kids: Drs. Emmanuelle Waubant and Jennifer Graves at the University of California at San Francisco and collaborators described preliminary results of a gene study in 117 children with MS, showing that one particular gene (rs4648356) was associated with lower rates of relapse, while another (rs11154801) was associated with higher rate of relapses. The study, which requires confirmation, was supported by the National MS Society and the Consortium of MS Centers. (Abstract P05.133)

## **Predictors/Disease Tracking Tools**

Tool to track progression: Dr. Nicholas LaRocca of the National MS Society described efforts of the newly formed MS Outcome Assessments Consortium to accelerate development of more effective treatments for MS, particularly for progressive forms of MS. MSOAC is a coalition of industry, academia, patient representatives, regulatory and other government agencies, and the National MS Society. In collaboration with the Critical Path Institute, they will analyze data from completed MS clinical trials and other studies and work with regulatory agencies to qualify a new clinician-reported outcome measure that can be used to more sensitively track the impact of therapy on disease disability and progression for future MS trials. (Abstract S31.001)

Predicting who will respond to Copaxone: Drs. Francisco Quintana, Howard Weiner and team at Harvard's Brigham and Women's Hospital described a study that analyzed serum samples from people with MS who were taking glatiramer acetate (Teva Pharmaceuticals). They were able to find antibody profiles that could detect those who responded to therapy and those who did not. Further work to confirm these findings could lead to a method to know early on whether a person is benefiting from this treatment or not. (Abstract S11.002)

## **RESTORING FUNCTION**

The broad area of research to restore function encompasses efforts to repair the nervous system and also stimulate recovery of lost function through exercise, rehabilitation and other means.

“Rewiring” the brain: Invited speaker Dr. Maria Assunta Rocca of San Raffaele Hospital in Milan, Italy presented compelling data for how the brain reorganizes to adapt to MS damage. In one study, the team looked at the impacts of a 12-week computer-assisted course that focused on training to increase memory and attention. They had previously reported improved attention and executive thinking abilities. Using functional MRI, which allows a real-time glimpse of the brain at work, they also found indicators that brain circuitry and activity had increased in specific areas, which appeared to persist at least 6 months after the training was completed. (Abstract P04.030)

Exercise and the brain: A small study from Society-supported scientists Drs. Victoria Leavitt, John DeLuca and others at the Kessler Foundation in New Jersey tested whether aerobic exercise impacts the brain. Using MRI scans and memory tests, they found hints that aerobic exercises (30 minute sessions, 3 times a week, over 3 months) improved memory and increased the volume of the hippocampus, a part of the brain involved with memory and other functions. These preliminary results require additional follow-up. (Abstract P04.034)

Exercise and fatigue: German researchers Drs. Stephan Schmidt of Bonn, and Marc Wonneberger of Cologne reported on the impacts of longer-term aerobic exercise to build endurance in people with MS. This study involved 60 people split into two groups: those with fatigue and those without fatigue. Both groups did individualized endurance exercise on treadmills for 12 months. After 6 months of exercise, both groups had improved oxygen consumption, but those who

started out with fatigue didn't show improvement in their fatigue scores until 9 months into the program. (Abstract P04.042)

Brain power: Researchers from Milan and from Kessler also reported that people with MS with more "brain reserve" (larger brain size) and more "cognitive reserve" (higher levels of cognitive leisure activities when they were in their 20s) were at lower risk for cognitive changes associated with MRI lesions. Even when brain size was accounted for, those with more cognitive reserve appear to have lower risk for cognitive changes. Research is ongoing to see whether enrichment activities can help build cognitive reserve. (Abstract P04.109)

CCSVI (<http://www.nationalmssociety.org/research/intriguing-leads-on-the-horizon/ccsvi/index.aspx>) treatment in MS: First results from a controlled endovascular treatment trial (percutaneous transluminal venous angioplasty) were presented by Drs. Robert Zivadinov, Adnan Siddiqui and the team from State University of New York at Buffalo. In this blinded study, 9 people had the angioplasty and 10 had a sham treatment. At six months, the team did not detect adverse events from the treatment, but also found that it failed to provide sustained improvement in venous outflow. They also found that those whose veins increased in outflow tended to have increased MS disease activity seen on MRI. (Emerging Science Poster P04.273)

Prevalence of CCSVI in MS: Dr. Robert Fox, Claude Diaconu and a team at Cleveland Clinic and Case Western Reserve reported preliminary results from a National MS Society-supported study of CCSVI in 61 people with different types of MS and 20 people without MS. They used ultrasound techniques that included technicians trained in CCSVI assessment who were unaware of the participants' disease status. Although changing the interpretation of CCSVI criteria produced substantial differences in the proportion of participants meeting those criteria (20% to 40% of non-MS met criteria versus 21.3% to 36.1% of MS participants), there was no significant difference between the non-MS and MS groups. (Abstract P05.177)

## ENDING MS FOREVER

There were several reports focusing on risk factors that may contribute to making a person more likely to get MS, including recaps of National MS Society-supported studies related to salt and MS immune activity <http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=7446>. This line of research could eventually lead to ways to prevent people from getting MS.

Dystel Prize: This year's winner of the John Dystel Prize for MS Research, given jointly by the National MS Society and the AAN, was Professor George Ebers of Oxford University, UK. He presented his work on the influences of genes and the environment in relation to who develops MS. Read about his work here (<http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=7517>).

Reproduction and risk of MS: Drs. Melinda Magyari, Per Solberg Sorensen and colleagues from the Danish MS Center in Copenhagen looked at potential factors that may account for an increased incidence of MS in women over several decades. Using the Danish MS Registry, which

captures info on most people in their country who have MS, they found that pregnancy and childbirth offered significant protection against developing MS, lasting up to 5 years. This and other studies can offer more clues to the influence of hormones and other factors in MS. (Abstract IN8-1.001)

Environmental exposures: Drs. Ellen Mowry at Johns Hopkins University, Lisa Barcellos at University of California, Berkeley and colleagues asked a proportion of women enrolled in Kaiser Permanente Northern California health care about their possible exposures to specific environmental factors. They adjusted results for some known risk factors such as genes already known to increase MS risk, vitamin D status, prior mononucleosis, and smoking in order to seek new possible factors. Results, which require further study, show that women exposed to small pets and reptiles may have been protected from developing MS, while those exposed to hair permanent solution may have had increased risk for developing MS. (Abstract P05.138)

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Copaxone is a registered trademark of Teva Pharmaceutical Industries

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## RESEARCH/CLINICAL UPDATE

**April 11, 2013**

### **New Study Reports That an Online Community of People with MS May Be Used to Study the Disease**

A new study finds that an online community of people registered with PatientsLikeMe™ is in some ways comparable to a patient population seen at a large MS center, and reports that a self-rating scale used by online participants may be useful in certain MS research investigations. Riley Bove, MD and Philip De Jager, MD, PhD (Brigham & Women's Hospital and Harvard Medical School, Boston) and colleagues published their findings in **PLOS ONE** (2013;8:e59707, <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0059707>). Dr. De Jager is a Harry Weaver Neuroscience Scholar of the National MS Society, and Dr. Bove is a recipient of the American Brain Foundation / National MS Society Clinician Scientist Grant (starting July 2013).

**Background:** PatientsLikeMe (<http://www.patientslikeme.com/>) is a for-profit company that offers a community for people with MS and other disorders, allowing them to create a personal profile and track disease progression, and engage in live discussion forums with other members of the MS community. At this writing, the MS Forum has 34,046 members. The site has a research team that conducts internal analyses, and collaborates with external research teams (such as in the current study). All data from the site is self-reported by people with MS and other disorders and caregivers. The PatientsLikeMe team developed the MS Rating Scale (MSRS) based on participant questionnaires, with the goal of developing an outcome measure that is easy to complete and measures a range of reported problems that might change over time, such as vision, cognition, sexual function, and bladder function.

**The Study:** The Brigham & Women's Hospital team selected people registered on PatientsLikeMe who reported a diagnosis of MS; were above the age of 18; provided at least 4 of the following personal characteristics: age, sex, disease type, age at first symptom, age at diagnosis; and had updated their profiles at least twice between 1/1/2009 and 8/31/2011. This total was 10,255 people. Demographic (age, race, ethnicity, gender, family history of MS, education) and disease

(disease type, age at first symptoms, use of disease modifying therapy) information were obtained from the PatientsLikeMe databases.

This population was compared with all patients older than 18 and diagnosed with MS who were seen at the Partners MS Center at Brigham and Women's Hospital, Harvard Medical School, at least twice in the two years prior to the study. There were 4,039 patients included.

In comparing these two populations, the Harvard team found small but statistically significant differences. PatientsLikeMe members were on average younger, more educated, more often female, and less often white. Their disease course was more often relapsing-remitting, with younger age at symptom onset and shorter disease duration, and a family history of MS was less common. Similar proportions of both populations used glatiramer acetate, but more PatientsLikeMe members used interferon beta. Knowing about these differences in the two study populations is a first step toward being able to understand and use the online community as a resource for certain research questions.

To assess the validity of the PatientsLikeMe MSRS rating scale questionnaire, 121 participants aged 18 or older and diagnosed with MS, who were seen in November 2011 at the Partners MS Center, and their physicians completed this questionnaire. The scores reported by patients and their physicians correlated strongly with each other, and with measures actually done in person, such as the EDSS, a standard scale used to measure MS disease progression.

Finally, as a test case, the team used this study to investigate a possible MS risk factor, body mass index (BMI). Because the prevalence of obesity has increased dramatically in the past several decades, and obesity is associated with an increase in immune system activity, researchers have sought to determine if there is any association between obesity and disease severity or progression. The team did not find a strong link between being overweight or obese and having worse MS severity or progression.

Comment: The authors caution that online research poses ethical and other challenges, such as issues of privacy, data storage, and inconsistent data sampling schedules. However, if such issues can be resolved, they conclude that PatientsLikeMe members offer an “intriguing new platform” for MS research. For example, using answers to the questionnaire over time with this tool may allow researchers to determine whether increases in certain symptoms such as fatigue may be early warning signs for clinical attacks, or be useful for evaluating a person’s response to therapy.

Read more about the connecting with the online MS community (<http://www.nationalmssociety.org/online-community/index.aspx>).



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## RESEARCH/CLINICAL UPDATE

April 15, 2013

### **Month of Birth May Influence Risk of MS by Promoting Changes in Immune System Development**

British researchers investigated why people born in May appear to have a higher risk of developing MS than those born in November. Based on tests done on umbilical cord blood from healthy babies, they suggest that those born in May tend to have higher levels of potentially harmful immune cells and lower levels of vitamin D in their blood, and that these factors may influence MS risk. If confirmed in larger studies, this offers more evidence for the interaction of environmental and genetic factors in MS. Research is ongoing in vitamin D and other factors that may control risks for developing MS. Giulio Disanto, MD, Sreeram Ramagopalan, DPhil, and colleagues at the University of Oxford and Queen Mary University of London published their study in the April 2013 issue of the JAMA Neurology (70(4):527-8

<http://www.ncbi.nlm.nih.gov/pubmed/23568650>).

Background: Many factors, including genetic and environmental factors (<http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/what-causes-ms/index.aspx>), probably affect the risk of developing MS. Vitamin D is an important nutrient that humans get from food, dietary supplements, and most importantly, from sun exposure. Research has increasingly indicated that lower levels of vitamin D in the blood are associated with a higher risk of developing MS. There have been several studies implicating a link between the month a person is born and the risk for developing MS. These studies suggest that people born in May have about a 20% increase risk of MS compared to people born in November.

The immune system is “educated” during development, both before and after birth, and this occurs in an immune organ call the thymus, located in front of the heart. When functioning properly, this thymic education determines the strength of a person’s immune response to foreign invaders like bacteria or viruses and even cancer cells. When it does not function properly, it can

lead to immune dysfunctions, such as occurs in MS. The proper balance of immune activity is regulated by immune genes, but the environment likely also plays an important role.

The authors of this study speculated that the month of birth effect was due to the influence of vitamin D (less sunlight exposure of the mother and lower vitamin D levels for the babies born in May compared to November) on the education of the immune response in the thymus before birth.

The Study: To begin to test this idea, the investigators obtained umbilical cord blood from 50 healthy babies born in May and 50 healthy babies born in November, and determined thymic function by measuring specific immune cells and other immune activity. They also measured vitamin D levels. They found that babies born in May had significantly higher levels of mature immune T cells (which have been implicated in MS and other immune-mediated diseases) than babies born in November. Babies born in May also had lower levels of vitamin D, suggesting that vitamin D might play a role in thymic function.

The small number of participants and the fact that all the babies came from one city (London) make it hard to know if this observation will be universal. Larger multicenter studies would be required to confirm this team's findings.

Comment: If confirmed, this observation could provide a rationale for giving vitamin D supplementation during pregnancy with the idea of lowering the baby's risk for MS in the future. More evidence would be necessary before such a recommendation could be made.

The National MS Society is funding several projects in this area, including a clinical trial underway (<http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=6264>) to test whether vitamin D can reduce disease activity in people who have MS. In 2011, the Society convened a summit (<http://www.nationalmssociety.org/news/news-detail/index.aspx?nid=5860>) to explore vitamin D trials farther.

Chronic excess vitamin D is associated with side effects, and some people cannot take supplements, so their use should be administered and monitored in consultation with a physician. Read more (<http://publications.nationalmssociety.org/momentum/mom2011summer#pg40>)



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## RESEARCH/CLINICAL UPDATE

**April 18, 2013**

### **National MS Society Partners with the University of Miami and Accera, Inc. to Test Novel “Medical Food” for MS Cognitive Impairment**

The National MS Society’s Fast Forward drug development subsidiary is partnering with Accera, Inc., and the University of Miami’s Miller School of Medicine in a clinical trial to determine potential benefits of Accera’s medical food, Axona<sup>®</sup> (caprylic triglyceride), on cognitive impairment in people with MS. Funding to test this novel dietary approach to a troubling MS symptom provides University of Miami with funding over a 36-month period, and like other Fast Forward ([www.fastforward.org](http://www.fastforward.org)) research partnerships, payments will be contingent upon the completion of specific milestones achieved during the trial.

**Novel Approach:** Axona is an FDA-regulated “medical food.” Axona has been approved by the FDA for management of biological processes associated with mild to moderate Alzheimer’s disease. As a medical food, Axona is intended to be used under physician supervision. It has not been approved by the FDA for use in MS.

Cognitive problems are a common symptom in individuals with MS and may have a negative impact on relationships, work, and quality of life. Treatment options are limited. Glucose (a type of sugar) is used to fuel the cells of the healthy brain. For people with neurological conditions such as MS, glucose may not be converted into energy as efficiently as it would be in a healthy brain, which can lead to a decrease in cognitive function. Axona may work to bypass this problem by providing an alternative energy source that is processed in the liver and used by the brain. This placebo-controlled study will be conducted by researchers at the University of Miami MS Center and will enroll 158 people with MS to determine whether Axona can help restore cognitive function to people with MS.

Researchers are recruiting trial participants in the local South Florida area who have MS and have experienced cognitive changes. For more information or to schedule a screening visit, contact the research Coordinator, Gloria Rodriguez at 305-243-8052 or by email at [GRodriguez13@med.miami.edu](mailto:GRodriguez13@med.miami.edu).

Read more about this project (PDF, <http://www.nationalmssociety.org/fast-forward/who-weve-funded/download.aspx?id=46517>).

## Frequently Asked Questions About the Axona Trial

### **Who can participate in the trial?**

People with any type of multiple sclerosis between the ages of 18-59, who have experienced any cognitive changes, may be eligible to participate.

### **How many people will participate in the study?**

This study will enroll 158 people with MS who have experienced cognitive problems.

### **How long will the trial last?**

The study will be open to enrollment for about two and a half years. Each participant will be enrolled in the study and receive either placebo or active treatment (Axona) for 90 days.

### **How many study visits are required?**

Each participant is asked to come for three study visits. The screening visit is about 1<sup>1/2</sup> hours and the other two visits will take between 2-3 hours.

### **Do all participants get Axona?**

This is a randomized double blind placebo controlled study. Half of the participants will be given Axona and half will be given placebo.

### **How is the study being funded?**

The project is being funded by Fast Forward, LLC, a nonprofit organization established by the National Multiple Sclerosis Society.

### **Is Caprylic Triglyceride effective?**

In clinical trials, Caprylic Triglyceride has been shown to improve cognitive function in certain people with mild to moderate Alzheimer's disease. Caprylic Triglyceride has never been studied in MS patients. This trial will begin to answer that question for patients with MS.

### **Are there any dietary restrictions for the study?**

Anyone allergic to milk or soy cannot take Axona. Axona does not contain gluten and only very low levels of lactose.

### **How is Caprylic Triglyceride administered?**

Axona comes as a vanilla-flavored powder that is usually mixed with 4 to 8 ounces of a liquid of one's choice, preferably after a meal. The placebo formulation will be appear and

taste identical to active treatment. Detailed instructions on how to take the treatment will be provided to participants.

### **Are there any side effects?**

Overall, Caprylic Triglyceride was well tolerated in clinical trials. The most common side effects were diarrhea, nausea, flatulence (gas), and stomach discomfort, which were generally considered mild to moderate. These side effects may be reduced if Caprylic Triglyceride is taken shortly after a meal. If you enroll in the study, the study doctors will provide instructions for taking the treatment and tips for reducing possible side effects.

### **How do I enroll?**

For more information, or to schedule a screening visit, please contact the research Coordinator, Gloria Rodriguez at 305-243-8052 or by email at [GRodriguez13@med.miami.edu](mailto:GRodriguez13@med.miami.edu).