



DEVELOPMENT

November 18, 2011

CC: All

November 2011: E-communications Update

November National MS eNEWS

Send date: 11/21/11

Audience: Full List

The November National MS eNEWS will be sent on Monday, November 21. Content includes a feature about MS pain – its many forms and causes, as well as news about potential new MS treatments in 2012 and a study about whether bacteria have a role in MS.

Notes

Individuals with a ‘no email’ classification on their Altair accounts will be suppressed, along with standard Direct Marketing Program excludes/suppressions.

A new FY 2012 Constituent Communications Calendar is posted on SharePoint at: Marketing → Society_Constituent_Communications_Calendar_and_Schedule_FY2012.

Contact Information

For editorial questions or suggestions regarding our National MS eNEWS, please contact Gary at gary.sullivan@nmss.org or 212-476-0538.

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



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RESEARCH/CLINICAL UPDATE

cc: Chapter President, Programs, Development

November 18, 2011

Positive Results Announced from Second Phase III Study of Alemtuzumab in MS

Genzyme has announced that the experimental intravenous therapy alemtuzumab (with a proposed brand name Lemtrada™) met two primary endpoints by significantly reducing relapse rates and the worsening of disability in a two-year study comparing alemtuzumab to standard subcutaneous dosing of Rebif® (interferon beta-1a, EMD Serono Inc. and Pfizer). The study, called CARE-MS II, involved 840 people with relapsing-remitting MS. The results were announced in a November 14, 2011 press release, which also indicated that the company plans to apply in early 2012 to the U.S. Food and Drug Administration for marketing approval. Data analysis is ongoing and the company expects to provide a full report at an upcoming medical meeting. Alemtuzumab has been designated by the FDA as a “Fast Track Product,” which should expedite its future review.

Background: MS involves immune system attacks against brain and spinal cord tissues. Alemtuzumab is a humanized monoclonal antibody directed at CD52 (a protein on the surface of immune cells) that is currently approved for the treatment of B-cell chronic lymphocytic leukemia. Its ability to target immune cells led investigators to test its potential as a treatment for relapsing-remitting MS. In an earlier phase II study comparing two dose levels of alemtuzumab with Rebif in 334 subjects with relapsing-remitting MS, those taking alemtuzumab had a 74% reduction in the risk of MS relapse compared with those on Rebif, and a 71% reduction in the risk for sustained worsening of disability (*New England Journal of Medicine* 2008 359;17:30-45).

Dosing was temporarily suspended in the Phase II study due to the occurrence of immune thrombocytopenic purpura (ITP), a rare condition in which low blood platelet counts can lead to abnormal bleeding. After the first cases of ITP occurred, one of which was fatal, Genzyme implemented a patient safety monitoring program which includes patient and physician education and regular contacts with patients.

Investigators recently reported on another phase III trial of alemtuzumab. The two-year CARE-MS-I phase III trial compared alemtuzumab against Rebif in 581 people with early relapsing-remitting MS. The study met one of two primary endpoints by reducing relapse rates by 55% over Rebif, but did not meet its second primary endpoint of slowing disease progression compared to Rebif. (Abstract #151,ECTRIMS 2011)

This Study: In the CARE-MS II study, 840 people with relapsing-remitting MS, who had experienced a relapse while on a prior therapy, were randomly assigned to receive alemtuzumab or Rebif. Alemtuzumab was given by intravenous infusion for 5 days initially and for 3 days one year later. Those on Rebif received the standard dose of 3-times weekly subcutaneous injections. According to the company press release, after two years the relapse rate of those on alemtuzumab was reduced by 49% compared to those on Rebif, and the risk of sustained worsening of disability (as measured by the EDSS scale) was reduced by 42% compared to Rebif. (These were the primary endpoints of the study.)

According to the press release, approximately 16% of those treated with alemtuzumab developed autoimmune thyroid-related problems and approximately 1% developed ITP. All cases were detected early through a monitoring program and managed with conventional therapies. Other common adverse events associated with alemtuzumab included reactions associated with infusions (such as headache, rash, fever, flushing, hives and chills). The most common infections in those treated with alemtuzumab (all mild to moderate) were upper respiratory and urinary tract infections, sinusitis and herpes simplex infections.

Comment: The completion of this second Phase III trial of alemtuzumab is a milestone that paves the way for the company to apply to the FDA for marketing approval. Full details and evaluation of this study should help define the safety and promise of alemtuzumab as a potential new therapy for relapsing MS.



MARKETING

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Awareness Video from National Conference 2011 now available

Thank you to everyone who participated in the National Conference, whether in person or through the recorded sessions at: www.nationalMSSociety.org/2011nationalconference).

As activist Sylvia Lawry demonstrated in 1946, we are each on the frontline of the MS Movement. We are each activists. We each have a critical role in bringing about a world free of multiple sclerosis. When we are connected, our collective impact is magnified – together we are exponentially more powerful.

Creating awareness is something each of us is committed to – and can take action on today. By lending our individual voices, each and every one of us can lay the groundwork for the most viral MS awareness activity to date – by simply sharing. Watch this new video, and then take action:

- Like, Favorite or +1 it.
- SHARE it. Whether through Facebook, YouTube, Google+, Twitter or other social media, SHARE! Retweet! Repost!
- And ask your connections to do the same.

(http://youtu.be/3gJ0mCY_Ado) YouTube video title: MS Impacts Us All

To help track and evaluate the impact of this video, please do not create a separate version or posting. Let's see how many people we can share this video with and create more awareness and understanding of MS.

- For questions about the video, Mark Serratoni, 303.698.6100 x15178 or mark.serratoni@nmss.org

- For questions about sharing, contact Beth Clark at beth.clark@nmss.org or Maura Dunn at maura.dunn@nmss.org.

*If you need a DVD of this video for off-line sharing, please contact Mark Serratoni.