TRI-STATE MULTIPLE SCLEROSIS ASSOCIATION

971-C S. Kenmore Drive
Evansville, IN 47714
Phone: 812-423-5943 Toll-Free: 1-866-514-4312
www.tristatems.org
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September 2020 Newsletter

Offering support, care, and hope…*right here at home!*

All Support Group Meetings and Newsletter Folding are Cancelled Until Further Notice!

We are continuing to work behind the scenes to make sure the telephone calls, emails, and office needs are being handled. It is important to us that we provide up-to-date information on our website and Facebook page for you. Please stay home, stay safe, and stay well!

Send your email address to officemanager@tristatems.org to receive newsletters and programs!

The Mission of the Tri-State Multiple Sclerosis Association is to enhance the quality of life for individuals living with MS & their families in Southern IN, Southern IL, & Western KY

CoViMS Registry for those with MS, and other CNS demyelinating diseases (Neuromyelitis Optica Spectrum Disease, or MOG antibody disease) who have developed COVID-19. Go to Covims.org. If you have MS and you come down with COVID-19 please report it on this website or ask your physician to do this.

*** This COViMS (COVID-19 Infections in MS & Related Diseases) is a joint effort of the National MS Society, the Consortium of MS Centers and the Multiple Sclerosis Society of Canada to capture information on outcomes of people with MS and other CNS demyelinating diseases (Neuromyelitis Optica Spectrum Disease, or MOG antibody disease) who have developed COVID-19.

WHAT YOU NEED to Know about Coronavirus COVID-19, if affected by Multiple Sclerosis

The Centers for Disease Control and Prevention (CDC) are following the outbreak of coronavirus (COVID-19), which causes a respiratory disease. This is a rapidly evolving situation and questions regarding the use of MS disease modifying therapies during this outbreak are being raised.

The National MS Society's National Medical Advisory Committee recommends the following:

1. **People with MS should follow** CDC guidelines and these additional recommendations for people at risk for serious illnesses from COVID-19.
2. **People with MS <u>should continue disease modifying therapies (DMTs)</u>** and discuss specific risks with their MS healthcare provider prior to stopping a DMT.
3. **Before starting a cell depleting DMT* or a DMT** that carries warnings of potentially severe increase in disability after stopping**, people with MS and their MS healthcare providers should consider specific risks (e.g. age, comorbid health conditions, location) and benefits.

* Cell depleting therapy: Lemtrada, Mavenclad, Ocrevus & Rituxan (used off-label in MS)

** DMTs with potentially severe increase in disability after stopping include: Gilenya and Tysabri.

These recommendations are the expert opinion of the National Medical Advisory Committee and are based on their clinical experience and assessment of the limited data available regarding COVID-19 and MS DMTs. They have been endorsed by the Consortium of Multiple Sclerosis Centers (CMSC) and members of the MS Coalition.

We are continuing to monitor this quickly evolving situation and these recommendations may be modified as more data becomes available.

Members of the MS Coalition include: Accelerated Cure Project for Multiple Sclerosis, Can Do MS, Consortium of Multiple Sclerosis Centers, International Organization of Multiple Sclerosis Nurses, Multiple Sclerosis Foundation, MS Views and News, Multiple Sclerosis Association of America, National Multiple Sclerosis Society and United Spinal Association

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*****Novartis announces publication of Phase III ASCLEPIOS trials demonstrating superior efficacy of ofatumumab in patients with relapsing multiple sclerosis**

- *Ofatumumab is a targeted B-cell therapy that delivers superior efficacy with a similar safety profile when compared with teriflunomide, a commonly prescribed oral treatment for MS*[1]
- *ASCLEPIOS I and II demonstrated significant reductions in risk of relapses, confirmed disability worsening and profound reduction of active or new brain lesions*[1]
- *The US Food and Drug Administration and European Medicines Agency are currently reviewing ofatumumab for the treatment of relapsing forms of MS (RMS) in adults*
- *If approved, ofatumumab will be the first B-cell therapy that can be self-administered at home and has the potential to become a first-choice treatment for use in RMS patients*

Basel, August 5, 2020 — Novartis today announced that *The New England Journal of Medicine* (NEJM) published the positive results from the ASCLEPIOS I and II studies evaluating the safety and efficacy of ofatumumab (OMB157) 20 mg monthly subcutaneous injections versus teriflunomide 14 mg oral tablets taken once daily in adults with relapsing forms of multiple sclerosis (RMS). Both studies met the primary endpoints where ofatumumab showed a significant reduction in the number of confirmed relapses, evaluated as the annualized relapse rate (ARR)[1].

“ASCLEPIOS I and II demonstrate the efficacy and safety of ofatumumab and its potential to become a first-choice treatment option that offers RMS patients the flexibility as they continue to live their lives,” said Krishnan Ramanathan, Neuroscience Global Program Head at Novartis. “Ofatumumab is a testament to our commitment to advance science and investigate potential treatments that reimagine care and address significant needs at all parts of the RMS journey.”

Results from the ASCLEPIOS I and II studies showed that compared with teriflunomide, ofatumumab:

- Significantly reduced the annualized relapse rate by 51% (0.11 vs 0.22) and 58% (0.10 vs 0.25) in ASCLEPIOS I and II, respectively.
- Showed a relative risk reduction of 34%) in 3-month confirmed disability worsening and 32% in 6-month confirmed disability worsening.

- Showed significant reduction of both gadolinium enhancing 1 lesions with a 97% and 94% relative reduction in ASCLEPIOS I and II, respectively, and an 82% and 85% relative reduction in new or enlarging T2 lesions in ASCLEPIOS I and II, respectively.
- Showed superiority in reducing neuroaxonal damage in both studies.
- Demonstrated a favorable trend in rate of 6-month confirmed disability improvement.
- Showed the annual rate of brain volume loss was not significantly different.
- Demonstrated an overall safety profile similar to teriflunomide, the frequency of serious infections and neoplasms was similar across both treatment groups. Injection-related reactions, nasopharyngitis, headache, injection-site reactions, upper respiratory tract infection and urinary tract infection were the most commonly observed adverse events across both treatment groups, occurring in ≥10% of patients.

"The ASCLEPIOS studies found that ofatumumab produced a significant reduction in new inflammation, as well as fewer clinical relapses and progression events," said Professor Stephen L. Hauser, Director of the UCSF Weill Institute for Neurosciences and co-chair of the steering committee for the ASCLEPIOS I and II studies. "A separate post hoc analysis demonstrated that nearly 9 out of 10 patients experienced no evidence of disease activity in the second year of treatment[4]. Ofatumumab represents a potential new option for RMS patients with greater efficacy compared to teriflunomide, a comparable safety profile, and the convenience of once monthly self-administration without the need for infusions."

This data was published in the August 6, 2020 issue of *The New England Journal of Medicine*

If approved, ofatumumab will be the first B-cell therapy that can be self-administered at and has the potential to become a first-choice treatment for use in RMS patients. Regulatory approval for ofatumumab in the US is expected in September 2020 and in Europe by Q2 2021. Novartis is committed to bringing ofatumumab to patients worldwide.

UPDATE **Basel, August 20, 2020** — Novartis today announced that the US Food and Drug Administration (FDA) has approved Kesimpta® (ofatumumab, formerly OMB157) as an injection for subcutaneous use for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Kesimpta is a targeted, precisely dosed and delivered B-cell therapy that has shown superior efficacy with a similar safety profile compared with teriflunomide and is a first-choice treatment option for RMS patients[1]. Kesimpta is the first B-cell therapy that can be self-administered once monthly at home via the Sensoready® autoinjector pen[3].

Upcoming Webinars

The Importance of a Proven Treatment (Sponsored by Biogen / Tysabri)

Date: September 2, 2020 / Time: 5:45 PM CST

Date: September 15, 2020 / Time: 7:45 PM CST

Date: September 21, 2020 / Time: 5:15 PM CST

Date: September 24, 2020 / Time: 10:45 AM CST

Registration: AboveMS.com, or call 1-866-955-9999.

Understanding Your MS

Date: September 3, 2020 / Time: 5:45 PM CST

MS expert Dr. Barbara Green, will discuss the goals of disease-modifying therapies, the importance of monitoring disease activity. To register for this webinar, sign up online at AboveMS.com, or call 1-866-955-9999.

Take Charge and Learn More About MS in African-Americans

Date: September 8, 2020 / Time: 5:45 PM CST

MS affects everyone differently. Recent research has uncovered information about MS in African-Americans. "Take Charge and Learn More About MS in African-Americans" (sponsored by Biogen) will take place with Dr. Mitzi Williams. You will learn about managing MS, recognizing symptoms, and discovering ways to approach your care. Registration: AboveMS.com.

Pain Management

Date: September 8, 2020 / Time: 7:00 PM - 8:15 PM CST

Presented by: Can-Do MS
Speakers: Aliza Ben-Zacharia, PhD, DNP, ANP, FAAN, MSCN and Abbey Hughes, PhD

Pain is an invisible symptom of MS. Explore management strategies for addressing this symptom and maintaining your quality of life. Register online at cando-ms.org

Understanding Silent Progression

Date: September 8, 2020 / Time: 5:30 PM CST

Participants will learn about the effects of inflammation early in the disease process and the potential consequences of silent progression. You'll then take a closer look at OCREVUS. Registration: Geniersvp.com Enter event code: 30895

Let's Talk Relapsing MS: What It Means to Be a Care Partner

Date: September 14, 2020 / Time: 7:15 PM CST

In this installment of Let's Talk Relapsing MS, we'll share tips and strategies for improving how care partners can communicate, help out, and plan ahead. There will also be a discussion about what care partners can do to care for themselves. Let's Talk Relapsing MS is hosted by Biogen®. Registration: AboveMS.com or call 1-866-955-9999.

Webinars from MS Views and News

Date: September 1, 2020 / Time: 7:00 PM CST

Speaker: Raick A. Harris, Psy D, Psychologist.
Learn more about relationships, family roles, friends work and self-care while living with MS. Registration: msviewsandnews.com

Date: September 3, 2020 / 6:00 PM CST

Speaker: Megan Weigel, DNP,MSCN
Discussion about brain health, healthy lifestyle choices and how it impacts wellness in MS. Also ways to reduce stress and incorporate self-care. Registration: msviewsandnews.com