

Your Abstract Submission Has Been Received

Print this page

You have submitted the following abstract to 2023 Annual Meeting of the Consortium of Multiple Sclerosis Centers. Receipt of this notice does not guarantee that your submission was complete or free of errors.

Five-Year Safety of Ofatumumab in People Living with Relapsing Multiple Sclerosis

Jeffrey A. Cohen, MD¹, Stephen L. Hauser, MD², Anne H. Cross, MD³, Kevin Winthrop, MD, MPH⁴, Heinz Wiendl, MD, PhD⁵, **Jacqueline Nicholas, MD, MPH⁶**, Sven G. Meuth, MD, PhD⁷, Paul S. Giacomini, MD⁸, Francesco Saccà, MD⁹, Ronald Zielman, MD, PhD¹⁰, Ayan Das Gupta, MSc¹¹, Xixi Hu, PhD¹², Roseanne Sullivan, PharmD¹², Virginia DeLasHeras, MD¹³ and Ludwig Kappos, MD¹⁴, (1)Department of Neurology, Mellen MS Center, Neurological Institute, Cleveland Clinic, Cleveland, OH, (2)UCSF Weill Institute for Neurosciences, Department of Neurology, University of California San Francisco, San Francisco, CA, (3)Washington University School of Medicine, St. Louis, MO, (4)Public Health and Preventive Medicine, Division of Infectious Diseases, Oregon Health and Sciences University, Portland, OR, (5)Department of Neurology with Institute of Translational Neurology, Medical Faculty, University Hospital, Münster, Germany, (6)OhioHealth Multiple Sclerosis Center, Columbus, OH, (7)Department of Neurology, Medical Faculty, Heinrich-Heine-University, Düsseldorf, Germany, (8)Department of Neurology and Neurosurgery, Montreal Neurological Institute, McGill University, Montreal, QC, Canada, (9)NSRO Department, University "Federico II" of Naples, Naples, Italy, (10)Novartis Pharma B.V., Amsterdam, Netherlands, (11)Novartis Healthcare Pvt. Ltd, Hyderabad, India, (12)Novartis Pharmaceuticals Corporation, East Hanover, NJ, (13)Novartis Pharma AG, Basel, Switzerland, (14)Research Center for Clinical Neuroimmunology and Neuroscience Basel (RC2NB), Departments of Head, Spine and Neuromedicine, Clinical Research, Biomedicine and Biomedical Engineering, University Hospital and University of Basel, Basel, Switzerland

Abstract Text:

Background: Previously reported safety data from ALITHIOS open-label extension study (NCT03650114) for up to 4 years demonstrated that extended treatment with ofatumumab continues to show a favorable safety and tolerability profile in people living with relapsing multiple sclerosis (RMS).

Objectives: To assess the longer-term safety and tolerability of ofatumumab treatment for up to 5 years in RMS participants.

Methods: Participants completing core ASCLEPIOS I/II (NCT02792218/NCT02792231), APOLITOS (NCT03249714) and APLIOS (NCT03560739) clinical trials may enter ALITHIOS. We previously reported cumulative safety data for up to 4 years of ofatumumab treatment in the overall (N = 1969), continuous (ofatumumab in core+extension; N = 1292) and newly switched (teriflunomide in core/ofatumumab in extension; N = 677) groups. Safety data for up to 5 years of ofatumumab treatment in the same study population will be presented at the congress. Proportion of participants with treatment-emergent adverse events (AEs), serious AEs (SAEs), injection-related reactions (IRRs), serious infections including opportunistic infections, malignancies, COVID-19 outcomes, serum immunoglobulin (Ig)G and IgM levels and their association with serious infections will be analyzed.

Results: In the previously reported 4-year safety data (cut-off: 25-Sep-2021), 86.2% had ≥ 1 AEs (exposure-adjusted incidence rate/100 patient-years [EAIR], 135.1) and 12.3% had ≥ 1 SAEs (EAIR, 5.0) with low incidence of serious infections (4.0%; EAIR, 1.5) and malignancies (0.9%; EAIR, 0.3). Majority (99.2%) of reported IRRs were mild-to-moderate in severity. Most COVID-19 cases were non-serious (90.2%) and majority (98.4%) were recovered. Mean serum IgG levels remained stable and greater than the lower limit of normal (LLN) (5.65 g/L). Mean serum IgM levels decreased over time but remained $>LLN$ (0.40 g/L). Safety data for up to 5 years will be presented at the congress.

Conclusions: Previously reported safety findings for up to 4 years showed ofatumumab treatment to be well-tolerated with no new safety risks identified. Additional safety data for up to 5 years will help inform physicians on the longer-term safety profile of ofatumumab in people living with RMS.

Title:

Five-Year Safety of Ofatumumab in People Living with Relapsing Multiple Sclerosis

Submitter's E-mail Address:

erin.moskal@envisionpharma.com

Preferred Presentation Format:

Poster

Category:

Disease-modifying therapy

Has this abstract been presented/published elsewhere prior to this meeting?:

No

Have you simultaneously submitted this abstract to another organization for consideration?:

Yes

Simultaneous submission details:

This abstract was originally submitted to AAN 2023 for consideration. At present and as of the of the CMSC submission deadline, it is currently unknown if abstract will be accepted by AAN. Please note, AAN notifications are anticipated in early Feb 2023 and the AAN meeting will take place April 22-27, 2023.

Would you give CMSC and International Journal of MS Care the first preference to any article that is submitted for publication based on this abstract presentation?:

No

Category: Disease-modifying therapy

Keywords:

Disease-modifying treatments in MS and Ofatumumab

First Author

Jeffrey Cohen, MD

Email: COHENJ@ccf.org -- Will not be published

Cleveland Clinic

Department of Neurology, Mellen MS Center, Neurological Institute

Cleveland OH

USA

[Click to view Conflict of Interest Disclosure](#)

Second Author

Stephen Hauser, MD

Email: Stephen.Hauser@ucsf.edu -- Will not be published

University of California San Francisco
UCSF Weill Institute for Neurosciences, Department of Neurology
San Francisco CA
USA

[Click to view Conflict of Interest Disclosure](#)

Third Author

Anne Cross, MD

Email: crossa@wustl.edu -- Will not be published

Washington University School of Medicine
St. Louis MO
USA

[Click to view Conflict of Interest Disclosure](#)

Fourth Author

Kevin Winthrop, MD, MPH

Email: winthrop@ohsu.edu -- Will not be published

Public Health and Preventive Medicine, Division of Infectious Diseases, Oregon Health
and Sciences University
Portland OR
USA

[Click to view Conflict of Interest Disclosure](#)

Fifth Author

Heinz Wiendl, MD, PhD

Email: heinz.wiendl@ukmuenster.de -- Will not be published

Department of Neurology with Institute of Translational Neurology, Medical Faculty,
University Hospital
Münster
Germany

[Click to view Conflict of Interest Disclosure](#)

Sixth Presenting Author

Presenting Author

Jacqueline Nicholas, MD, MPH

Email: Jacqueline.Nicholas@ohiohealth.com -- Will not be published

OhioHealth Multiple Sclerosis Center
Columbus OH
USA

[Click to view Conflict of Interest Disclosure](#)

Seventh Author

Sven Meuth, MD, PhD

Email: meuth@uni-duesseldorf.de -- Will not be published

Department of Neurology, Medical Faculty, Heinrich-Heine-University
Düsseldorf
Germany

[Click to view Conflict of Interest Disclosure](#)

Eighth Author

Paul Giacomini, MD

Email: paul.giacomini@mcgill.ca -- Will not be published

Department of Neurology and Neurosurgery, Montreal Neurological Institute, McGill
University
Montreal QC
Canada

[Click to view Conflict of Interest Disclosure](#)

Ninth Author

Francesco Saccà, MD

Email: francesco.sacca@unina.it -- Will not be published

NSRO Department, University "Federico II" of Naples
Naples
Italy

[Click to view Conflict of Interest Disclosure](#)

Tenth Author

Ronald Zielman, MD, PhD

Email: ronald.zielman@novartis.com -- Will not be published

Novartis Pharma B.V.
Amsterdam
Netherlands

[Click to view Conflict of Interest Disclosure](#)

Eleventh Author

Ayan Das Gupta, MSc

Email: ayan.das_gupta@novartis.com -- Will not be published

Novartis Healthcare Pvt. Ltd
Hyderabad
India

[Click to view Conflict of Interest Disclosure](#)

Twelfth Author

Xixi Hu, PhD

Email: xixi.hu@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

[Click to view Conflict of Interest Disclosure](#)

Thirteenth Author

Roseanne Sullivan, PharmD

Email: roseanne.sullivan@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

[Click to view Conflict of Interest Disclosure](#)

Fourteenth Author

Virginia DeLasHeras, MD

Email: virginia.delasheras@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

[Click to view Conflict of Interest Disclosure](#)

Fifteenth Author

Ludwig Kappos, MD

Email: ludwig.kappos@usb.ch -- Will not be published

Research Center for Clinical Neuroimmunology and Neuroscience Basel (RC2NB),
Departments of Head, Spine and Neuromedicine, Clinical Research, Biomedicine and
Biomedical Engineering, University Hospital and University of Basel
Basel
Switzerland

[Click to view Conflict of Interest Disclosure](#)

First Contact

Jacqueline Nicholas, MD, MPH

Email: Jacqueline.Nicholas@ohiohealth.com -- Will not be published

OhioHealth Multiple Sclerosis Center
Columbus OH
USA

Second Contact

Erin Moskal, BA

Email: erin.moskal@envisionpharma.com -- Will not be published

Alternate Email: EnvisionNovartisNeurology@envisionpharma.com -- Will not be published

Envision Pharma Group
Fairfield CT
USA

If necessary, you can make changes to your abstract submission.

To access your submission in the future, use the direct link to your abstract submission from one of the automatic confirmation emails that were sent to you during the submission.

Or point your browser to </cmssc/reminder.cgi> to have that URL mailed to you again. Your username/password are 8844/459379.

Any changes that you make will be reflected instantly in what is seen by the reviewers. You DO NOT need to go through all of the submission steps in order to change one thing. If you want to change the title, for example, just click "Title" in the abstract control panel and submit the new title.

When you have completed your submission, you may close this browser window.

[Tell us what you think of the abstract submission process](#)

[Home Page](#)