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COVID-19 Outcomes and Vaccination Status in Patients with Relapsing Multiple Sclerosis Receiving Ofatumumab

Kevin Winthrop, MD, MPH¹, Silvia Delgado, MD², Mario Habek, MD³, Maria Davydovskaya, PhD⁴, Brian Ward, MD⁵, Bruce A. C. Cree, MD, PhD⁶, Natalia Totolyan, MD⁷, Linda Mancione, BA⁸, Roseanne Sullivan, PharmD⁸, Ronald Zielman, MD, PhD⁹, Xixi Hu, PhD⁸, Ayan Das Gupta, MSc¹⁰, Xavier Montalban, MD PhD¹¹ and Anne Cross, MD¹², (1)Public Health and Preventive Medicine, Division of Infectious Diseases, Oregon Health and Sciences University, Portland, OR, (2)University of Miami Miller School of Medicine, Miami, Florida, USA, FL, (3)University Hospital Center Zagreb, University of Zagreb, School of Medicine, Zagreb, Croatia, Croatia, (4)Moscow state Public Healthcare InszCity Clinical Hospital 24, Moscow, Russia, Russian Federation, (5)Infectious Diseases Division, Research Institute of the McGill University Health Centre, Montreal, QC, Canada, (6)Neurology, UCSF Weill Institute for Neurosciences, Department of Neurology, University of California San Francisco, California, USA, San Francisco, CA, (7)First Saint Petersburg State Medical University, St Petersburg, Russian Federation, (8)Novartis Pharmaceuticals Corporation, East Hanover, NJ, (9)Novartis Pharma B.V., Amsterdam, Netherlands, (10)Novartis Healthcare Pvt. Ltd, Hyderabad, India, (11)Department of Neurology-Neuroimmunology, Centre d'Esclerosi Múltiple de Catalunya (Cemcat), Hospital Universitari Vall d'Hebron, Barcelona, Spain, (12)Neurology, Washington University School of Medicine, Saint Louis, St. Louis, MO

Abstract Text:

Background: With increasing focus on COVID-19 and the introduction of vaccines, further evidence is required to better understand the effect of COVID-19 and vaccination in multiple sclerosis (MS) patients treated with disease-modifying therapies. Data collected since the start of the pandemic to 29-Jan-2021 on the COVID-19 outcomes in ofatumumab-treated relapsing MS (RMS) patients has previously been reported.

Objectives: To report COVID-19 outcomes, vaccination status, and breakthrough infections in patients with RMS on ofatumumab from the ALITHIOS study and post-marketing setting.

Methods: Demographics, baseline characteristics, incidence of COVID-19, severity and outcomes were analyzed from the ongoing, open-label, long-term extension ALITHIOS study and the post-marketing setting (Cut-off date: 25-Sep-2021). Reinfection, vaccination rates and breakthrough infections have also included in this analysis.

Results: In ALITHIOS study, 245/1703 patients (14.3%) (mean±SD age at baseline: 37.9±8.75 years; female, 69.8%) receiving ofatumumab had confirmed (n=210; 85.7%) or suspected (35; 14.3%) COVID-19. Most COVID-19 cases were non-serious (221; 90.2%) and 23 (9.4%) patients were hospitalized. Most reported cases were mild/moderate (Grade 1/2) in severity (90.6%); 19 (7.8%) had severe (Grade 3) and 3 (1.2%) had life-threatening (Grade 4) COVID-19. Most patients had recovered/recovered with sequelae/were recovering (241/245; 98.4%); 2 (0.8%) had not recovered, and 2 (0.8%) had fatal outcomes. COVID-19 led to temporary ofatumumab interruption in 39 patients (15.9%) and discontinuation in 2 patients (0.8%), who were fatal. No patients had COVID-19 reinfection.

Overall, 559/1703 (32.8%) patients were vaccinated (fully vaccinated, 476; partially vaccinated, 74; unspecified, 9). Breakthrough infections occurred in 7 (1.5%) patients and 11 (1.97%) patients had infection after partial vaccination; all patients recovered.

From the post-marketing setting, 90 confirmed COVID-19 cases were reported. Of these, 10 (11.1%) were serious cases. No life-threatening or fatal cases were reported. Among known

outcomes (N=36), most recovered/recovered with sequelae/were recovering (n=30). One mild breakthrough COVID-19 case was reported and recovered.

Conclusions: Based on this updated data, there does not appear to be an increased risk of severe COVID-19 or fatal outcomes in RMS patients treated with ofatumumab. A very small number of vaccinated patients had breakthrough infections, and all recovered.

Title:

COVID-19 Outcomes and Vaccination Status in Patients with Relapsing Multiple Sclerosis Receiving Ofatumumab

Submitter's E-mail Address:

vaishnavi.khandal@novartis.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:

European Academy of Neurology - 8th Congress (Date of the program: June 25-28)

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:

COVID-19 and Disease-modifying treatments in MS

First Presenting Author

Presenting 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

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Any relevant financial relationships? Yes

Organization Name	Relationship
BMS, Pfizer	Contracted Research
Pfizer, AbbVie, Union ChimiqueBelge, Eli Lilly & Company, Galapagos, GlaxoSmithKline, Roche, Gilead, BMS, Regeneron, Sanofi, AstraZeneca, Novartis	Honoraria

Second Author

Silvia Delgado, MD

Email: sdelgado1@med.miami.edu -- Will not be published

University of Miami Miller School of Medicine
Miami, Florida, USA FL
USA

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Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis	Consulting Fee
University of Miami from EMD Serono, MAPI Pharma, and Novartis	Site Principal Investigator of Research grant

Third Author

Mario Habek, MD

Email: mario.habek@mef.hr -- Will not be published

University Hospital Center Zagreb, University of Zagreb, School of Medicine
Zagreb, Croatia
Croatia

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Any relevant financial relationships? Yes

Organization Name	Relationship
Biogen, Sanofi Genzyme, Merck, Bayer, Novartis, Pliva/Teva, Roche, Alvogen, Actelion, Alexion Pharmaceuticals, and TG Pharmaceuticals	Consulting Fee
Biogen, Sanofi Genzyme, Merck, Bayer, Novartis, Pliva/Teva, Roche, Alvogen, Actelion, Alexion Pharmaceuticals, and TG Pharmaceuticals	Clinical investigator

Fourth Author

Maria Davydovskaya, PhD

Email: mdavydovskaya@gmail.com -- Will not be published

Moscow state Public Healthcare InszCity Clinical Hospital 24
Moscow, Russia
Russian Federation

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Any relevant financial relationships? Yes

Organization Name	Relationship
Biogen Idec, Celgene/Receptos, Janssen/Actelion, Merck/EMD Serono, Novartis, Roche Sanofi Genzyme, and TG Pharmaceuticals	Consulting Fee
Biogen Idec, Merck/EMD Serono	Advisory board member
Medicine Association of Professional and MS centers	President

Fifth Author

Brian Ward, MD

Email: brian.ward@mcgill.ca -- Will not be published

Infectious Diseases Division, Research Institute of the McGill University Health Centre
Montreal QC
Canada

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Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis	Received fees to serve on a scientific advisory board
Medicago Inc	Received a salary as medical officer
Vaccines targeting influenza, Clostridioides difficile and Schistosoma mansoni	Receipt of Intellectual Property Rights/Patent Holder
Medicago, MIT Canada, and Aviex Technologies	Held Academic industry award

Sixth Author

Bruce A. C. Cree, MD, PhD
Email: Bruce.Cree@ucsf.edu -- Will not be published

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

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Any relevant financial relationships? Yes

Organization Name	Relationship
Alexion, Atara, Autobahn, Avotres, Biogen, EMD Serono, Horizon, Neuron23, Novartis, Sanofi, TG Therapeutics and Therini	Consulting Fee
Alexion, Atara, Autobahn, Avotres, Biogen, EMD Serono, Horizon, Neuron23, Novartis, Sanofi, TG Therapeutics and Therini	Received personal compensation
Genentech	Received research support

Seventh Author

Natalia Totolyan, MD
Email: ntotolyan@mail.ru -- Will not be published

First Saint Petersburg State Medical University
St Petersburg

Russian Federation

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Any relevant financial relationships? Yes

Organization Name	Relationship
Merck and Novartis	Received Fees for advisory board or speaking
Alexion, BIOCAD, Janssen, MAPI Pharma, Merck, Novartis, Receptos, Roche, Sanofi, and TG Therapeutics	Received Institutional grants for conducting clinical trial

Eighth Author

Linda Mancione, BA

Email: linda.mancione@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

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

Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis	Employee

Ninth 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](#)

Any relevant financial relationships? Yes

--

Organization Name	Relationship
Novartis	Employee and has Novartis stock ownership

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](#)

Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis	Employee

Eleventh 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](#)

Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis	Employee

Twelfth 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](#)

Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis	Employee

Thirteenth Author

Xavier Montalban, MD PhD

Email: Xavier.montalban@cem-cat.org -- Will not be published

Centre d'Esclerosi Múltiple de Catalunya (Cemcat), Hospital Universitari Vall d'Hebron
Department of Neurology-Neuroimmunology
Barcelona
Spain

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Any relevant financial relationships? Yes

Organization Name	Relationship
Abbvie, Actelion, Alexion, Bayer, Biogen, Bristol-Myers Squibb/Celgene, EMD Serono, Genzyme, Hoffmann-La Roche, Immunic, Janssen Pharmaceuticals, Medday, Merck, Mylan, Nervgen, Novartis, Sandoz, Sanofi-Genzyme, Teva Pharmaceutical and TG Therapeutic	Consulting Fee
Biogen, Hoffmann-La Roche, Sanofi-Genzyme, Merck, Novartis, Teva Pharmaceutical	Contracted research funded through the institution
Abbvie, Actelion, Alexion, Bayer, Biogen, Bristol-Myers Squibb/Celgene, EMD Serono, Genzyme, Hoffmann-La Roche, Immunic, Janssen Pharmaceuticals, Medday, Merck, Mylan, Nervgen, Novartis, Sandoz, Sanofi-Genzyme, Teva Pharmaceutical and TG Therapeutics	Received speaking honoraria and travel expenses for participation in scientific meetings, has been a steering committee member of clinical trials or participated in advisory boards of clinical trials with these organizations
Excemed	Speaking Honoraria

Fourteenth Author

Anne Cross, MD

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

Washington University School of Medicine, Saint Louis
Neurology
St. Louis MO
USA

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Any relevant financial relationships? Yes

Organization Name	Relationship
Biogen, EMD Serono, Genentech/Roche, Horizon Pharma, Novartis	Consulting Fee
EMD Serono, Genentech/Roche	Contracted Research
EMD Serono	Scientific advisory Board of EVOLUTIONRMS study
Genentech/Roche	Scientific advisory board for OBOE study
Novartis	Scientific Advisory Board for Asclepius I and II
Academic CME (CE provider)	Speaking, preparation of slides for CME talk
CME Outfitters, LLC, 201 N King of Prussia Rd, Ste 370, Radnor PA 19087 (CE provider)	Talked at CME session online
Consortium of MS Centers; 3 University Plaza Dr, Ste 116, Hackensack NJ 07601	Gave CME at Orlando meeting, Secretary of Board of Councilors of CMSC
Projects in Knowledge (CE provider)	Preparation of educational manuscripts, activities

First Contact

Vaishnavi Khandal, M. Pharm

Email: vaishnavi.khandal@novartis.com -- Will not be published

Novartis
Hyderabad
India

Second Contact

Ronald Zielman, MD, PhD
Email: ronald.zielman@novartis.com -- Will not be published

Novartis Pharma B.V.
Amsterdam
Netherlands

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