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Injection-Related Reactions with Subcutaneous Administration of Ofatumumab in Relapsing Multiple Sclerosis: Pooled Analysis of the Phase 3 Asclepios I and II Trials

Ratnakar Pingili, MD[1], Amit Bar-Or, MD, FRCPC[2], Jeffrey A. Cohen, MD[3], Patricia K. Coyle, MD[4], Anne H. Cross, MD[5], Stephen L. Hauser, MD[6], Ludwig Kappos, MD[7], Cecile Kerloeguen, MSc[8], Ayan Das Gupta, MS Stats[9], Valentine Jehl, MSc[8], Dieter A. Haering, PhD[8], Krishnan Ramanathan, PhD[8] and Martin Merschhemke, MD[8], (1)Novartis Pharmaceuticals Corporation, East Hanover, NJ, (2)Center for Neuroinflammation and Experimental Therapeutics and Department of Neurology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, (3)Department of Neurology, Mellen MS Center, Neurological Institute, Cleveland Clinic, Cleveland, OH, (4)Department of Neurology, Stony Brook University, Stony Brook, NY, (5)Department of Neurology, Division of Neuroimmunology, Washington University School of Medicine, St Louis, MO, (6)Department of Neurology, UCSF Weill Institute for Neurosciences, University of California San Francisco, San Francisco, CA, (7)Neurologic Clinic and Policlinic, Departments of Medicine, Clinical Research, Biomedicine and Biomedical Engineering, University Hospital and University of Basel, Basel, Switzerland, (8)Novartis Pharma AG, Basel, Switzerland, (9)Novartis Healthcare Pvt. Ltd., Hyderabad, India

Abstract Text:

Background:

Ofatumumab, the first fully human anti-CD20 monoclonal antibody, with a monthly 20 mg subcutaneous (s.c.) dosing regimen, demonstrated superior efficacy (reductions in clinical relapses by 51%–59%, disability worsening by 33%–34%, and gadolinium-enhancing lesions by 94%–98%) versus teriflunomide in the two Phase 3 ASCLEPIOS I/II relapsing multiple sclerosis (RMS) trials. Injection-related reactions (IRRs) were the most common adverse events (AEs) observed.

Objectives:

To characterize the risk of IRRs (systemic and local site reactions) observed with ofatumumab in RMS patients.

Methods:

In the pooled ASCLEPIOS I/II trials, patients were randomized (1:1) to receive s.c. ofatumumab 20 mg (n=946) (loading dose: Days 1, 7 and 14; maintenance dose: every 4 weeks from Week 4) or oral teriflunomide 14 mg once daily (n=936), for up to 30 months. Patients in the teriflunomide group received matching placebo injections. All patients received the first four injections at the clinic and subsequent injections at home. Premedication was recommended, but not mandatory. Both systemic (during and within 24 hours post injection) and local site IRRs (at any time) were reported.

Results:

In the ofatumumab group, 20.6% (n=195) of the patients, and 15.3% (n=143) in the teriflunomide group experienced ≥1 systemic IRR. Incidence of systemic IRRs with the first injection was 14.4% with ofatumumab versus 7.5% with teriflunomide. The incidence of systemic IRRs decreased with subsequent doses and was similar to the matching placebo injections in the teriflunomide group. The majority of IRRs (99.8%) were Grade 1/2 in severity; Grade 3 IRRs were observed in two patients (0.2%) with ofatumumab at the first injection (one of which was reported as a serious AE) versus none with teriflunomide. One additional IRR (Grade 1) was also reported as a serious AE with ofatumumab. The serious IRRs (0.2%) were manageable and patients continued treatment with no recurrences. No life-threatening IRRs were reported during the study. The most frequent (≥2%) IRR symptoms observed with ofatumumab were fever, headache, myalgia, chills, and fatigue. Majority of local site IRRs were mild to moderate in severity and non-serious in nature; the most frequently reported symptoms (≥2%) included erythema, pain, itching, and swelling.

Conclusions:

Systemic and local IRRs with ofatumumab 20 mg s.c. were mostly mild to moderate in severity. Beyond the first injection, IRRs were no more frequent with ofatumumab versus matching placebo injections.

Title:
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Submitter's E-mail Address:
ratnakar.pingili@novartis.com

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First Presenting Author

Presenting Author

Ratnakar Pingili, MD
Email: ratnakar.pingili@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

Click to view Conflict of Interest Disclosure

Second Author

Amit Bar-Or, MD, FRCPC
Email: amitbar@pennmedicine.upenn.edu -- Will not be published

Center for Neuroinflammation and Experimental Therapeutics and Department of Neurology, Perelman School of Medicine, University of Pennsylvania
Philadelphia PA
USA

Click to view Conflict of Interest Disclosure

Third Author

Jeffrey Cohen, MD
Email: cohenj@ccf.org -- Will not be published

Department of Neurology, Mellen MS Center, Neurological Institute, Cleveland Clinic
Cleveland OH
USA

Biographical Sketch Cleveland, OH

Click to view Conflict of Interest Disclosure

Fourth Author

Patricia Coyle, MD
Email: Patricia.Coyle@stonybrookmedicine.edu -- Will not be published

Department of Neurology, Stony Brook University
Stony Brook NY
USA

Click to view Conflict of Interest Disclosure

Fifth Author

Anne Cross, MD
Email: crossa@neuro.wustl.edu -- Will not be published

Department of Neurology, Division of Neuroimmunology, Washington University School of Medicine
St Louis MO
USA

Click to view Conflict of Interest Disclosure

Sixth Author

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

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

Click to view Conflict of Interest Disclosure

Seventh Author

Ludwig Kappos, MD
Email: ludwig.kappos@usb.ch -- Will not be published

Neurologic Clinic and Policlinic, Departments of Medicine, Clinical Research, Biomedicine and Biomedical Engineering, University Hospital and University of Basel
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Eighth Author

Cecile Kerloeguen, MSc
Email: cecile.kerloeguen@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Ninth Author

Ayan Gupta, MS Stats
Email: ayan.das_gupta@novartis.com -- Will not be published
Novartis Healthcare Pvt. Ltd.
Hyderabad
India

Click to view Conflict of Interest Disclosure

Tenth Author

Valentine Jehl, MSc
Email: valentine.jehl@novartis.com -- Will not be published
Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Eleventh Author

Dieter Haering, PhD
Email: dieter.haering@novartis.com -- Will not be published
Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Twelfth Author

Krishnan Ramanathan, PhD
Email: krishnan.ramanathan@novartis.com -- Will not be published
Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Thirteenth Author

Martin Merschhemke, MD
Email: martin.merschhemke@novartis.com -- Will not be published
Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

First Contact

Ratnakar Pingili, MD
Email: ratnakar.pingili@novartis.com -- Will not be published
Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

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