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Injection-Related Reactions with Subcutaneous Administration of Ofatumumab in Relapsing Multiple Sclerosis: Data from Clinical Studies and Post Marketing Experience

John F Kramer, PA-C[1], Patrick Vermersch, MD, PhD[2], Roseanne Sullivan, PharmD[3], Ronald Zielman, MD, PhD[4], Xixi Hu, PhD[3], Ayan Das Gupta, MSc[5], Wendy Su, PhD[3], Dee Stoneman, MPharm[6], Elisabeth B Lucassen, MD[3] and Olaf Hoffmann, PD Dr. med.[7], (1)St Thomas Medical Partners, Nashville, TN, (2)Univ. Lille, Inserm U1172 LilNCog, CHU Lille, FHU Precise, Lille, France, (3)Novartis Pharmaceuticals Corporation, East Hanover, NJ, (4)Novartis Pharma B.V., Amsterdam, Netherlands, (5)Novartis Healthcare Pvt. Ltd, Hyderabad, India, (6)Novartis Pharma AG, Basel, Switzerland, (7)Department of Neurology, Alexianer St. Josefs Hospital, Potsdam, Germany

Abstract Text:

Background:

In the ASCLEPIOS I/II trials, injection-related reactions (IRRs; systemic and local-site) with ofatumumab were predominantly reported with the first injection. Most IRRs were mild-to-moderate in severity and non-serious in nature. No life-threatening/hypersensitivity reactions leading to discontinuation were observed. Updated data on IRRs is available from the open-label extension study, ALITHIOS, and in the post-marketing setting.

Objectives:

To report the potential risk of IRRs observed in relapsing multiple sclerosis (RMS) patients treated with ofatumumab, including newly-switched patients in the ALITHIOS trial and in the post-marketing setting.

Methods:

Data from the core ASCLEPIOS I/II, APLIOS, APOLITOS trials and ALITHIOS study (overall, N=1969; patients who received continuous ofatumumab, N=1292; patients newly switched from teriflunomide to ofatumumab, N=677) and from the post-marketing setting (cut-off: 25 Sep 2021) were included in this analysis. Incidence of both systemic and local-site IRRs, severity, seriousness and discontinuations were reported. The most commonly associated symptoms have also summarized.

Results:

Systemic/local-site IRRs were observed in 24.7%/11.8% in the overall population; 25.7%/13.5% in continuous and 22.9%/8.6% in newly-switched groups. Upon first injection, incidence of systemic/local-site IRRs in overall, continuous, and newly-switched groups were 17.4%/3.0%, 17.0%/3.4%, and 18.3%/2.2%, respectively. These rates decreased with subsequent injections. Majority of IRRs (99.4%) were mild-to-moderate (Grade 1/2) in severity. No life-threatening IRRs were observed. Four patients (0.6%) with systemic IRRs and 1 patient (0.1%) with local-site IRRs discontinued the treatment in newly-switched group. The most common systemic IRR symptoms (≥5%) were fever, headache, chills, fatigue, and local-site IRR symptoms (≥3%) were erythema/redness and pain. In the post-marketing setting, with an estimated exposure of 4,713 patient-years, no medically confirmed fatal or life-threatening IRRs were identified. There were 8 medically confirmed serious cases: 7 patients were hospitalized, 1 patient in which the events were determined to be medically significant but did not require hospitalization.

Conclusions:

Systemic and local-site IRRs reported upon first injection with ofatumumab in the core clinical studies and ALITHIOS trial, including in newly-switched patients and in the post-marketing setting

were mostly mild-to-moderate in severity.

Title:
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Submitter's E-mail Address:
thakur.amitha_singh@novartis.com

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First Presenting Author

Presenting Author

John Kramer, PA-C
Email: jfkramer75@gmail.com -- Will not be published

St Thomas Medical Partners
Nashville TN
USA

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Second Author

Patrick Vermersch, MD, PhD
Email: patrick.vermersch@univ-lille2.fr -- Will not be published

Univ. Lille, Inserm U1172 LilNCog, CHU Lille, FHU Precise
Lille
France

Click to view Conflict of Interest Disclosure

Third 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

Fourth 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

Fifth 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

Sixth 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

Seventh Author

Wendy Su, PhD
Email: wendy.su@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

Click to view Conflict of Interest Disclosure

Eighth Author

Dee Stoneman, MPharm
Email: dee.stoneman@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Ninth Author

Elisabeth Lucassen, MD
Email: elisabeth.lucassen@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

Click to view Conflict of Interest Disclosure

Tenth Author

Olaf Hoffmann, PD Dr. med.
Email: olaf.hoffmann@charite.de -- Will not be published

Department of Neurology, Alexianer St. Josefs Hospital
Potsdam
Germany

Click to view Conflict of Interest Disclosure

First Contact

John Kramer, PA-C
Email: jfkramer75@gmail.com -- Will not be published

St Thomas Medical Partners
Nashville TN
USA

Second Contact

Amitha Thakur, Mpharm.
Email: thakur.amitha_singh@novartis.com -- Will not be published

Novartis
Hyderabad
India

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