Your Abstract Submission Has Been Received

Print this page

You have submitted the following abstract to 2021 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.

Comparable Ofatumumab Treatment Outcomes in Patients across Racial/Ethnic Groups in the Asclepios I/II and Apolitos Studies

Silvia Delgado, MD[1], Mitzi J Williams, MD[2], Morten Bagger, PhD[3], Gordon Graham, PhD[3], Etienne Pigeolet, PhD[3], Huixin Yu, PhD[3], Dieter A. Haering, PhD[3], Roman Willi, PhD[3], Cecile Kerloeguen, MSc[3], Chao Xu, PhD[4], Masaru Hirano, PhD[5], Dee Stoneman, MPharm[3], Wendy Su, PhD[6], Krishnan Ramanathan, PhD[3] and Jin Nakahara, MD, PhD[7], (1)Neurology, University of Miami Miller School of Medicine, Miami, FL, (2)Joi Life Wellness MS Center, Atlanta, GA, (3)Novartis Pharma AG, Basel, Switzerland, (4)China Novartis Institute of Biomedical Research, Shanghai, China, (5)Novartis Pharmaceutics, K.K., Tokyo, Japan, (6)Autoimmune, TG Therapeutics, Inc, New York, NY, (7)Department of Neurology, Keio University School of Medicine, Tokyo, Japan

Abstract Text:

Background:

Ofatumumab is a fully human anti-CD20 monoclonal antibody approved by the FDA for treatment of adults with relapsing multiple sclerosis (RMS). The RMS disease course and treatment response may vary across different racial/ethnic groups.

Objectives:

To compare outcomes across different racial/ethnic patient groups with RMS following ofatumumab treatment.

Methods:

This post hoc analysis included data from patients treated with ofatumumab 20 mg subcutaneously in the Phase 3 ASCLEPIOS I/II studies (n=935; White [n=829], Black/African-American [n=28], Asian [n=36], other [n=42]) and Phase 2 APOLITOS study (n=43; White [n=22], Asian [n=21, Japanese]). We compared efficacy, pharmacokinetics (PK), pharmacodynamics (PD), and safety outcomes for ofatumumab by these patient groups.

Results:

In ASCLEPIOS I/II, annualized relapse rates (95%CI) were similar in White (0.13 [0.11; 0.15]), Black/African-American (0.07 [0.02; 0.22], Asian (0.08 [0.03; 0.24]), and other (0.08 [0.03; 0.18]) patients treated with ofatumumab. As per PK analysis, ofatumumab trough concentrations (median [95%CI]) were comparable in White (0.438 [0.05; 2.53] µg/mL), Black/African-American (0.106 [0.05; 1.67] µg/mL), Asian (0.127 [0.05; 1.20] µg/mL) and other (0.453 [0.05; 2.25] µg/mL) patients in ASCLEPIOS I/II, with numerically higher concentrations (0.713 [0.142; 2.00] µg/mL) observed in Asian patients in APOLITOS. A population-PK analysis demonstrated a statistically significant difference between Japanese and Caucasian PK parameters but no clinically significant difference for maximum serum concentrations and area under the curve in these two populations. In APOLITOS, ofatumumab was associated with a consistent depletion of CD19+ B-cells and CD3+CD20+ T-cells in Asian and White patients, indicating similar PD response. No meaningful differences were observed in the incidence of adverse events (AEs) in ASCLEPIOS I/II (White [84.9%], Black/African-American [92.9%], Asian [66.7%], other [69.8%]) nor in APOLITOS. Overall pattern, incidence rate and severity of AEs across the groups was consistent with the overall population with no discernible trends/safety signals.

Conclusions:

Results revealed no clinically relevant differences in outcomes for RMS patients of different racial/ethnic groups treated with ofatumumab 20 mg subcutaneously, suggesting dose adjustment

may not be necessary across these groups.

Title:
Comparable Ofatumumab Treatment Outcomes in Patients across Racial/Ethnic Groups in the Asclepios I/II and Apolitos Studies

Submitter's E-mail Address:
meredith.whitaker@alphabet-health.com

Preferred Presentation Format:
Poster

Category:
Disease-modifying therapy

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?:
Yes

Category: Disease-modifying therapy
Keywords:
Disease-modifying treatments in MS and Racial/ethnic subgroups

<u>First Presenting Author</u>
Presenting Author

Silvia Delgado, MD
Email: sdelgado1@med.miami.edu -- Will not be published

University of Miami Miller School of Medicine
Neurology
Miami FL
USA

Click to view Conflict of Interest Disclosure

Second Author

Mitzi Williams, MD
Email: mitzijwilliamsmd@gmail.com -- Will not be published

Joi Life Wellness MS Center
Atlanta GA
USA

Click to view Conflict of Interest Disclosure

Third Author

Morten Bagger, PhD
Email: morten.bagger@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Fourth Author

Gordon Graham, PhD
Email: gordon.graham@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Fifth Author

Etienne Pigeolet, PhD
Email: etienne.pigeolet@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

    Click to view Conflict of Interest Disclosure

Sixth Author

Huixin Yu, PhD
Email: huixin.yu@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

    Click to view Conflict of Interest Disclosure

Seventh 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

Eighth Author

Roman Willi, PhD
Email: roman.willi@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

    Click to view Conflict of Interest Disclosure

Ninth 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

Tenth Author

Chao Xu, PhD
Email: chao-1.xu@novartis.com -- Will not be published

China Novartis Institute of Biomedical Research
Shanghai
China

Click to view Conflict of Interest Disclosure

Eleventh Author

Masaru Hirano, PhD
Email: masaru.hirano@novartis.com -- Will not be published

Novartis Pharmaceutics, K.K.
Tokyo
Japan

Click to view Conflict of Interest Disclosure

Twelfth 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

Thirteenth Author

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

TG Therapeutics, Inc
Autoimmune
New York NY
USA

Click to view Conflict of Interest Disclosure

Fourteenth 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

Fifteenth Author

Jin Nakahara, MD, PhD
Email: nakahara@a6.keio.jp -- Will not be published

Keio University School of Medicine
Department of Neurology
Tokyo
Japan

Click to view Conflict of Interest Disclosure

First Contact
_____

Meredith Whitaker, PhD
Email: meredith.whitaker@alphabet-health.com -- Will not be published

Alphabet Health
New York NY
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 /cmsc/reminder.cgi to have that URL mailed to you again. Your username/password are 7352/.

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