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Longer-Term Effects of Ofatumumab on Clinical and MRI Outcomes in Patients with Relapsing Multiple Sclerosis

Derrick Robertson, MD, College of Medicine, Neurology, University of South Florida, Tampa, FL, Stephen L Hauser, PhD, UCSF Weill Institute for Neurosciences, University of California, San Francisco, CA, Edward J. Fox, MD, PhD, Central Texas Neurology Consultants, University of Texas Medical Branch, Round Rock, TX, Ludwig Kappos, MD, Research Center for Clinical Neuroimmunology and Neuroscience Basel (RC2NB) and MS Center, Departments of Head, Spine and Neuromedicine, Clinical Research, Biomedicine and Biomedical Engineering, University Hospital and University of Basel, Basel, Switzerland, Jeffrey A Cohen, MD, Mellen MS Center, Cleveland Clinic, Cleveland, OH, Angela Aungst, MPH, Multiple Sclerosis Division Department of Neurology University of South Florida, Florida, FL, Wendy Su, PhD, Novartis Pharmaceuticals Corporation, East Hanover, NJ, Ronald Zielman, MD, PhD, Novartis Pharma B.V., Amsterdam, Netherlands, Jing Xi, PhD, China Novartis Institutes For Biomedical Research Co., Ltd., Shanghai, China, Ayan Das Gupta, MSc, Novartis Healthcare Pvt. Ltd., Hyderabad, India and Dee Stoneman, MPharm, Novartis Pharma AG, Basel, Switzerland

Abstract Text:

Background:

The Phase 3 ASCLEPIOS I/II trials demonstrated the superiority of ofatumumab versus teriflunomide in patients with relapsing multiple sclerosis (RMS) by reducing annualized relapse rate (ARR), suppressing MRI lesion activity and delaying disability worsening, while maintaining a favorable safety profile. Evaluation of the longer-term efficacy of ofatumumab treatment continues to be important.

Objectives:

To assess the longer-term efficacy of ofatumumab treatment for up to 4 years in patients with RMS.

Methods:

This analysis will include cumulative data from patients randomized to ofatumumab/teriflunomide in the ASCLEPIOS I/II trials (core study) and followed up to data cut-off: 25-Sep-2021, the majority patients had entered the ongoing, open-label, ALITHIOS extension study. In ALITHIOS, patients randomized to ofatumumab in the core study continued with ofatumumab treatment (continuous group) and those randomized to teriflunomide in the core study were switched to ofatumumab (switch group). ARR, disability worsening (time-to-3-month/6-month confirmed disability worsening), disability improvement (time-to-6-month confirmed disability improvement), and MRI outcomes (number of Gd+T1 lesions and annualized T2 lesion rate) will be assessed.

Results:

Of 1882 patients randomized in the ASCLEPIOS I/II trials (ofatumumab/teriflunomide: 946/936), 1367 patients enrolled into ALITHIOS (continuous/switch: 690/677; 88.8% ongoing for both groups). Baseline demographics and disease characteristics of the continuous (baseline from core) and switch (baseline from extension) groups include: mean age, ~38 years (continuous), ~40 years (switch); female, ~67% (both groups); mean BMI, ~26 kg/m^2 (both groups); mean EDSS, ~2.9 (both groups); treatment-naive patients, 40.8% (continuous) and 38.8% (switch; baseline from core); mean number of Gd+T1 lesions, 1.7 (continuous) and 0.8 (switch); mean volume of T2 lesions, 13.7 cm^3 (continuous) and 12.6 cm^3 (switch; baseline from core); treatment

exposure, 2761.4 PY (continuous) and 1271.1 PY (switch). Updated efficacy results for up to 4 years of ofatumumab treatment will be presented at the congress.

Conclusions:

These analyses will provide further insights on the longer-term effects of continuous ofatumumab treatment for up to 4 years, and the effects of switching from teriflunomide to ofatumumab and providing further evidence to support the benefit/risk profile of ofatumumab.

Title:
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Submitter's E-mail Address:
venkateswarlu.bonala@novartis.com

Preferred Presentation Format:
Platform/Oral

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:
American Academy of Neurology, European Academy of Neurology

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 Long-term clinical effects

First Presenting Author

Presenting Author

Derrick Robertson, MD
Email: dsrobert@usf.edu -- Will not be published

University of South Florida
College of Medicine, Neurology

Tampa FL
USA

Click to view Conflict of Interest Disclosure

Second Author

Stephen Hauser, PhD
Email: stephen.hauser@ucsf.edu -- Will not be published

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

Click to view Conflict of Interest Disclosure

Third Author

Edward Fox, MD, PhD
Email: FoxTexMS@gmail.com -- Will not be published

University of Texas Medical Branch
Central Texas Neurology Consultants
Round Rock TX
USA

Click to view Conflict of Interest Disclosure

Fourth Author

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

Research Center for Clinical Neuroimmunology and Neuroscience Basel (RC2NB) and MS Center, 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

Fifth Author

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

Mellen MS Center, Cleveland Clinic
Cleveland OH
USA

Click to view Conflict of Interest Disclosure

Sixth Author

Angela Aungst, MPH
Email: aaungst@usf.edu -- Will not be published

Multiple Sclerosis Division Department of Neurology University of South Florida
Florida FL
USA

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

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

Ninth Author

Jing Xi, PhD
Email: jing.xi@novartis.com -- Will not be published

China Novartis Institutes For Biomedical Research Co., Ltd.
Shanghai
China

Click to view Conflict of Interest Disclosure

Tenth 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

Eleventh 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

First Contact

Venkateswarlu Bonala, M. Pharm
Email: venkateswarlu.bonala@novartis.com -- Will not be published

Novartis
Hyderabad
India

Second Contact

Derrick Robertson, MD
Email: dsrobert@usf.edu -- Will not be published

University of South Florida
College of Medicine, Neurology
Tampa FL
USA

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