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Olikos Study Design: Exploring Maintained Ofatumumab Efficacy in Relapsing MS Patients Who Transition from Intravenous Anti-CD20 Therapy

Le H Hua, MD[1], Enrique Alvarez, MD, PhD, MSCI[2], Roland G Henry, PhD[3], Joel Brown, PhD, PharmD[4], Elizabeth Camacho, MBA[4], Xiangyi Meng, PhD[4], Marina Ziehn, PhD[5], Brandon Brown, PharmD[4] and Benjamin M Greenberg, MD, MHS[6], (1)Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, (2)Department of Neurology, University of Colorado, Aurora, CO, (3)UCSF Neurology, Weill Institute for Neurosciences, San Francisco, CA, (4)Novartis Pharmaceuticals Corporation, East Hanover, NJ, (5)Novartis Pharma AG, Basel, Switzerland, (6)Neurology & Neurotherapeutics - MS Clinic, UT Southwestern Medical Center, Dallas, TX

Abstract Text:

Background:

B-cell depletion in patients with relapsing multiple sclerosis (RMS) using anti-CD20 monoclonal antibodies (mAbs) reduces annualized relapse rates and inflammatory lesion activity on MRI, and delays time to confirmed disability worsening. Anti-CD20 mAbs ocrelizumab and rituximab are administered intravenously in clinic; ofatumumab is administered subcutaneously with an autoinjector pen, facilitating patient-administration at home. No outcome data exist relating to transition from ocrelizumab/rituximab treatment to ofatumumab.

Objectives:

OLIKOS, a 12-month, prospective, single-arm, multicenter Phase 3b study, will explore maintained efficacy in patients with RMS transitioning from intravenous anti-CD20 mAb therapy to ofatumumab.

Methods:

Approximately 100 adults with RMS will be enrolled at 10-20 US centers. Eligible patients will have been previously treated with at least 2 consecutive courses of ocrelizumab/rituximab, with last dose 4-9 months before OLIKOS baseline. Other inclusion criteria are EDSS score ≤5.5 at screening and stable disease while on prior anti-CD20 therapy. Patients with suboptimal response to anti-CD20 therapy (relapse, ≥2 active gadolinium-enhancing [Gd+] lesions, any new/enlarging T2 lesions, clinical worsening), or who discontinued anti-CD20 therapy because of severe infusion-related reactions or recurrent infections, or with progressive disease, will be excluded. All participants will receive ofatumumab 20 mg via autoinjector on Days 1, 7, and 14, then once monthly through Month 12. The primary endpoint will be no change or a reduction in Gd+ lesion count at Month 12. Secondary endpoints will be participant retention and changes in immune biomarkers, treatment satisfaction, safety, and tolerability at Months 6 and 12. There will be a 6-month interim analysis.

Results:

The detailed study design for the OLIKOS trial will be presented. The trial will generate efficacy, retention, and satisfaction data from RMS patients transitioning from intravenous anti-CD20 therapies to ofatumumab.

Conclusions:

OLIKOS will provide important data on the maintenance of efficacy in RMS patients transitioning from intravenous anti-CD20 therapies to ofatumumab.

Title:
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Submitter's E-mail Address:
grace.jeong@alphabet-health.com

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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

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First Presenting Author

Presenting Author

Le Hua, MD
Email: Hual@ccf.org -- Will not be published

Cleveland Clinic Lou Ruvo Center for Brain Health
Las Vegas NV
USA

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Bristol Myers Squibb	Speakers Bureau
Genzyme	Speakers Bureau

Second Author

Enrique Alvarez, MD, PhD, MSCI
Email: enrique.alvarez@cuanschutz.edu -- Will not be published

University of Colorado
Department of Neurology
Aurora CO
USA

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TG Therapeutics	Compensation for activities such as advisory boards, lectures and consultancy
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Genentech/Roche	Contracted Research
Novartis	Contracted Research
TG Therapeutics	Contracted Research
Patient-Centered Outcomes Research Initiative	Contracted Research
National Multiple Sclerosis Society	Contracted Research
National Institutes of Health	Contracted Research
Rocky Mountain MS Center	Contracted Research

Third Author

Roland Henry, PhD
Email: Roland.Henry@ucsf.edu -- Will not be published

Weill Institute for Neurosciences
UCSF Neurology
San Francisco CA
USA

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Genentech, Inc.	Contracted Research
Novartis	Contracted Research
Celgene	Contracted Research
Atara	Contracted Research

Fourth Author

Joel Brown, PhD, PharmD
Email: joel.brown@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

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Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis Pharmaceuticals Corporation	Salary

Fifth Author

Elizabeth Camacho, MBA
Email: elizabeth.camacho@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	Salary

Sixth Author

Xiangyi Meng, PhD
Email: xiangyi.meng@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

Biographical Sketch East Hanover, NJ

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Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis	Salary

Seventh Author

Marina Ziehn, PhD
Email: marina.ziehn@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis AG	Salary

Eighth Author

Brandon Brown, PharmD
Email: brandon.brown@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

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Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis	Salary
Novartis	Ownership Interest

Ninth Author

Benjamin Greenberg, MD, MHS
Email: benjamin.greenberg@utsouthwestern.edu -- Will not be published

UT Southwestern Medical Center
Neurology & Neurotherapeutics - MS Clinic
Dallas TX
USA

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Any relevant financial relationships? Yes

Organization Name	Relationship
Novartis	Consulting Fee
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First Contact

Le Hua, MD
Email: Hual@ccf.org -- Will not be published

Cleveland Clinic Lou Ruvo Center for Brain Health
Las Vegas NV
USA

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