Suggested title:

OLIKOS study design: exploring maintained ofatumumab efficacy in relapsing MS patients who transition from intravenous anti-CD20 therapy

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Abstract

Background: Depletion of B cells in patients with relapsing multiple sclerosis (RMS) using anti-CD20 monoclonal antibodies (mAbs) reduces annualized relapse rates and inflammatory lesion activity on magnetic resonance imaging, and delays time to confirmed disability worsening. Anti-CD20 mAbs ocrelizumab and rituximab are administered by intravenous infusion in clinic; ofatumumab is administered subcutaneously with a pre-filled syringe or autoinjector (AI) pen, facilitating self-administration. No outcome data exist relating to transition of patients treated with ocrelizumab or rituximab to ofatumumab.

Objectives: OLIKOS is a 12 month, prospective, single-arm, multicenter phase 3b study that will explore maintained efficacy of ofatumumab in patients with RMS who transition from intravenous anti-CD20 mAb therapy.

Methods: About 100 adults with RMS will be enrolled at 10-20 centers in the USA. Eligible patients will have been previously treated with 2-5 consecutive courses of intravenous ocrelizumab or rituximab (other anti-CD20 mAbs are excluded), with last dose 4-9 months before OLIKOS baseline. Other inclusion criteria are Expanded Disability Status Scale score 5.5 or lower at screening and CD19 B cells depleted to below 1% at baseline. Patients with
suboptimal response to anti-CD20 therapy in the previous 6 months (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 subcutaneous ofatumumab 20 mg administered by AI pen on Days 1, 7 and 14, then monthly in Months 1-12. 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 will be presented. OLIKOS will complement the ofatumumab phase 3 program in RMS by generating maintained efficacy, retention and satisfaction data based on monthly subcutaneous drug delivery with the AI pen in patients previously treated with ocrelizumab or rituximab.

Conclusions: OLIKOS will provide important data on the maintained efficacy of ofatumumab in patients with RMS transitioning from intravenous anti-CD20 therapies.

Title character count: 136 / 150 (including spaces)

Main text character count: 2,476 / 2,500 (including spaces)

Supported by: Novartis Pharmaceuticals Corporation

Disclosure statement
Benjamin M. Greenberg has received consulting fees from Alexion, EMD Serono, Novartis, Viela Bio, Roche, Greenwich Bio, Axon Advisors, Rubin Anders and Abcam. He has received grant support from the NIH, NMSS, SRNA, GuthyJackson Charitable Foundation, PCORI and CLENE Nanomedicine. He serves as an unpaid board member of the Seigel Rare Neuroimmune Association.

Enrique Alvarez has received consulting fees from Actelion/Janssen, Alexion, Bayer, Biogen, Celgene/BMS, EMD Serono/Merck, Genentech/Roche, Genzyme, Novartis, and TG Therapeutics. He has received research grants and/or participated in studies sponsored by Biogen, Genentech/Roche, Novartis, TG Therapeutics, Patient-Centered Outcomes Research Institute, National Multiple Sclerosis Society, National Institutes of Health, and Rocky Mountain Multiple Sclerosis Center
John Foley has received speaker, advisory board and consulting fees from Alexion, Biogen, EMD Serono, Genzyme, and Novartis. He receives research funds from Adamas, Biogen, Genentech, Novartis, and Octave.

Roland Henry has received consulting fees and/or research funding from ATARA Bio, Celgene, MEDDAY, Novartis, Roche/Genentech and Sanofi-Genzyme.

Joel Brown, Elizabeth Camacho, Xiangyi Meng, Marina Ziehn and Brandon Brown are employees of Novartis Pharmaceuticals Corporation.

Le H Hua has received speaker, advisory board and consulting fees from Biogen, Bristol Myers Squibb, EMD Serono, Genentech, Novartis, Sanofi Genzyme and VielaBio.

Preferred format: Oral presentation

Suggested topic: Clinical Trials

Available topics:
- Biomarkers and Bioinformatics
- Biosensors
- Biostatistical Methods
- Clinical Outcome Measures
- Clinical Trials
- Comorbidities
- Diagnostic Criteria and Differential Diagnosis
- Disease Modifying Therapies – Mechanism of Action
- Disease Modifying Therapies – Risk Management
- Epidemiology
- Experimental Models
- Gender Differences, Hormones and Sex Chromosomes
- Genetics and Epigenetics
- Imaging
- Internet and Social Media
- Machine Learning/Network Science
- Microbiome
- Metabolomics
- Neuromyelitis Optica and Anti-MOG Disease
- Neuro-Ophthalmology
- Neuroprotection, Regeneration and/or Remyelination
- Neuropsychology and Cognition
- Observational Studies
- Pathogenesis – Immunology
- Pathogenesis – Neurodegeneration
- Pathogenesis – Role of Glia
- Pathogenesis – the Blood-Brain Barrier
- Pediatric MS
- Prognostic Factors
- Patient-Reported Outcomes and Quality of Life
- Rehabilitation and Comprehensive Care
- Reproductive Aspects and Pregnancy
- Symptom Management