Suggested title:

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

Authors

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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.

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Disclosure statement

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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