MSMilan2023
9th Joint ECTRIMS-ACTRIMS Meeting
11–13 October 2023 | Milan, Italy

Abstract Number: [3057]

Abstract Title: OLIKOS Study: 6-Month Interim Efficacy and Safety in Patients With Relapsing Multiple Sclerosis Who Switched to Subcutaneous Ofatumumab From Intravenous Anti-CD20 Therapies

Abstract Category: Late Breaking Abstracts - 43 - Late Breaking Abstracts

Preferred Presentation Type: Oral or poster presentation

Le Hua*[1], Brandon Brown[2], Elizabeth Camacho[2], Benjamin M. Greenberg[3], Roland Henry[4], Rebecca Piccolo[2], Enrique Alvarez[5]

[1]Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, United States, [2]Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States, [3]Department of Neurology, University of Texas Southwestern Medical Center, Neurology, Dallas, TX, United States, [4]UCSF Weill Institute for Neurosciences, Department of Neurology, University of California, San Francisco, CA, United States, [5]The Rocky Mountain MS Center at the University of Colorado, Anschutz Medical Campus, Aurora, CO, United States

Introduction:
Anti-CD20 therapies are effective in the treatment of relapsing multiple sclerosis (RMS). Unlike ocrelizumab (OCR) and rituximab (RTX), which are administered intravenously (IV), ofatumumab (OMB) is administered subcutaneously (SC) via autoinjector pen. Maintenance of efficacy, safety and patient satisfaction with OMB in patients with RMS transitioning from IV anti-CD20 therapy was assessed in OLIKOS (NCT04486716), a single-arm, open-label, phase 3b study.

Objectives/Aims:
Describe interim efficacy and safety results for patients enrolled in OLIKOS who completed the first 6 months of the study.

Methods:
OLIKOS enrolled patients (18-60 years) with RMS who received ≥2 courses of IV anti-CD20 therapy (OCR or RTX). Patients were required to be stable on their previous therapy and switched for reasons other than safety or lack of efficacy. Eligible patients received OMB 20 mg SC via autoinjector, with standard loading and monthly maintenance doses over 1 year. Patient demographic and clinical characteristics were recorded at baseline (BL). The primary endpoint was the proportion of patients with no change or reduction in the number of gadolinium-enhancing (Gd+) lesions on magnetic resonance imaging (MRI) from BL to Month 12. Safety endpoints included treatment-emergent adverse events (TEAEs). Exploratory endpoints included change in immunoglobulin (Ig) G and IgM levels.

Results:
This abstract reports on 65 of 111 enrolled OLIKOS patients with completed 6-month data. In this subset (n=65) the mean (SD) age at BL was 43 (8.4) years and most patients were White (72.3%) and female (64.6%); all patients previously received OCR before switching to OMB. Median (range) BL Expanded Disability Status Scale score and mean (SD) disease duration were 3.5 (0.0–5.5) and 8.8 (7.0) years, respectively. At BL, mean (SD) number of Gd+ T1 lesions was 0.02 (0.1), and IgG and IgM levels (g/L) were 10.3 (3.0) and 0.5 (0.3), respectively. At 6 months, all patients with available Gd+ T1

lesion data (n=51) met the primary endpoint (95% CI: 0.93-1.00). TEAEs occurred at the same frequency as in the phase 3 clinical trials, with no new safety signals identified. 6-month mean (SD) IgG and IgM levels (g/L; n=63) were 10.1 (3.0) and 0.5 (0.3), respectively. Interim results for all 111 patients will be presented.

Conclusion:

OMB 20 mg SC maintained efficacy at 6 months in patients with RMS transitioning from IV anti-CD20 therapies, as demonstrated by no new MRI activity. No new safety signals were identified, and Ig levels remained stable.

Disclosures: Le H. Hua: Received personal fees for speaking, consulting, and advisory board activities from Alexion, Bristol Myers Squibb, EMD Serono, Genentech, Genzyme, Greenwich Biosciences, Horizon Therapeutics and Novartis; and has had research support paid to her institution from Biogen.
Brandon Brown: Employee of and stockholder in Novartis Pharmaceuticals Corporation.
Elizabeth Camacho: Employee of and stockholder in Novartis Pharmaceuticals Corporation.
Benjamin M. Greenberg: Received consulting fees from Alexion, Arialys, Bayer, Clene, Cycle Pharma, EMD Serono, Genentech/Roche, Genzyme, Horizon Therapeutics, Immunovant, Intervenn, IQVIA, Janssen, Novartis, PHAR, PRIME Education, Sandoz, Signant, Syneos and TG Therapeutics; received grant funding from Anokion, National Institutes of Health and Regeneron; serves as an unpaid member of the board of the Siegel Rare Neuroimmune Association; has equity in Clene and GenrAb; and receives royalties from UpToDate.
Roland G. Henry: Received consulting fees and/or research funding from Atara Biotherapeutics, Boston Pharmaceuticals, Celgene, Genentech/Roche, MedDay, Neurona Therapeutics, Novartis, QIA Consulting and Sanofi Genzyme.
Rebecca Piccolo: Employee of and stockholder in Novartis Pharmaceuticals Corporation.
Enrique Alvarez: Received consulting fees from Actelion/Janssen, Alexion, Bayer, Biogen, Celgene/Bristol Myers Squibb, EMD Serono/Merck, Genentech/Roche, Genzyme, Horizant, Novartis and TG Therapeutics; and has received research grants and/or participated in studies sponsored by Biogen, Genentech/Roche, National Institutes of Health, National Multiple Sclerosis Society, Novartis, Patient-Centered Outcomes Research Institute, Rocky Mountain MS Center and TG Therapeutics.