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

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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:

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