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Ofatumumab Effectiveness and Safety in Relapsing Multiple Sclerosis Patients with Breakthrough Disease on Oral Fumarates or Fingolimod: Artios Interim Analysis

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Abstract Text:
Background:

In the ASCLEPIOS I/II Phase 3 trials, there was a limited number of patients with relapsing multiple sclerosis (RMS) switching to ofatumumab from oral therapies due to breakthrough disease. The ARTIOS study aims to bridge this gap.

Objectives:

To assess the effectiveness and safety of subcutaneous ofatumumab 20 mg in RMS patients with breakthrough disease on oral fumarates/fingolimod.

Methods:

ARTIOS, an ongoing Phase 3b open-label, single-arm, non-comparative study, includes adult RMS patients with breakthrough disease on fumarates/fingolimod who transitioned to ofatumumab at the start of the study (planned enrollment, N=555). Patients receive ofatumumab once every 4 weeks (following an initial dose regimen in the first month) for up to 96 weeks. This interim analysis was conducted after ~50% of planned enrolled subjects completed the Week 48 visit + 28 days of follow up for relapses and adverse events (AEs). Annualized relapse rates (ARR), MRI lesion activity, disease progression, serum neurofilament light chain (NfL), IgG/IgM levels, and safety including AEs were analyzed. Safety data were also analyzed by fumarate or fingolimod subgroups.

Results:

This analysis included 278 patients (mean age: 37.4 years; mean exposure: 52 weeks). Adjusted ARR was low at 0.12 (95% CI: 0.08, 0.18]) and met the nominal threshold for significance (p=0.023 [null hypothesis ARR≥0.18]). Ofatumumab significantly reduced Gd+T1 (by 97% versus baseline) and new/enlarging T2 lesions; EDSS remained stable. Only 9 patients (<4%) experienced 6-month confirmed disability worsening over a period of 1 year. Mean serum NfL levels decreased below baseline by Week 24. Overall, 88.1% of patients reported any AE, most of which were mild/moderate in severity [93.9%]; commonly reported AEs [≥15% of patients] were systemic injection-related reactions, COVID-19, and headache. SAE incidence was low (3.2%). Only one patient discontinued treatment due to AEs. Analysis by prior use of fumarate or fingolimod subgroup showed a similar trend. Mean serum IgG levels

remained stable and above LLN; mean IgM levels decreased from baseline to Week 48 (mean IgM at Week 48: 0.783 g/L) but remained above LLN. In 97.8% and 81.7% of patients IgG/IgM levels, respectively, remained above LLN over the analysis period.

Conclusions:

This ARTIOS interim analysis indicates that ofatumumab reduces disease activity in RMS patients with breakthrough disease activity on oral fumarates/fingolimod. No new safety signals were observed compared with the ASCLEPIOS results.

Title:
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Disease-modifying therapy

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