Longer-term Efficacy of Ofatumumab in Patients with Relapsing Multiple Sclerosis

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INTRODUCTION

The Phase 3 ASCLEPIOS I/II trials demonstrated the superiority of ofatumumab versus teriflunomide in reducing annualised relapse rate (ARR), suppressing MRI lesion activity and delaying disability worsening while maintaining a favourable safety profile in patients with relapsing multiple sclerosis (RMS). Here, we assess the longer-term efficacy of ofatumumab treatment for up to 4 years.

DESIGN/METHODS

Cumulative data from patients randomised to ofatumumab/teriflunomide in the ASCLEPIOS I/II trials (core study) and the ongoing, open-label, ALITHIOS extension study will be analysed (data cut-off: 25-Sep-2021). Patients randomised to ofatumumab in the core and potentially continued in the extension (continuous group) and to teriflunomide in the core with potential switch to ofatumumab in the extension (switch group) will be included. ARR, disability worsening (time-to-3-month/6-month confirmed disability worsening), disability improvement (time-to-6-month confirmed disability improvement), and brain MRI outcomes (number of Gd+T1 lesions and annualised T2 lesion rate) will be reported.

RESULTS

Of the 1882 patients randomised in the ASCLEPIOS I/II trials (ofatumumab/teriflunomide: 946/936), 1367 patients enrolled into ALITHIOS (continuous/switch: 690/677; both groups, 88.8% ongoing). The **Table** shows baseline demographics and disease characteristics of these patients. Updated efficacy results for up to 4 years of ofatumumab treatment will be presented at the congress.

CONCLUSIONS

This study was funded by Novartis Pharma AG, Basel, Switzerland

These analyses will provide further insights on longer-term efficacy of continuous ofatumumab treatment for up to 4 years, and the effects of switching from teriflunomide to ofatumumab and add valuable information for the assessment of Ofatumumab's benefit/risk profile.

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TABLES/FIGURES

Table. Baseline Demographics and Disease Characteristics

	Ofatumumab continuous (N=946)	**Ofatumumab Switched from Teriflunomide (N=936)**	
		Baseline from core study (N=936)	**Baseline from extension study (N=677)**
Age, years*	38.4±9.04	38.0±9.22	40.1±9.21
Female, n (%)	637 (67.3)	636 (67.9)	456 (67.4)
BMI, kg/m^2*	25.86±6.22	25.93±6.02	25.61±5.85
Mean exposure, years*	2.9±1.31[a]	1.5±0.5[b]	1.9±0.50[c]
Patient-years	2761.4[a]	1397.8[b]	1271.1[c]
Treatment-naive patients[#], n (%)	386 (40.8)	363 (38.8)	NA
EDSS score at baseline*	2.93±1.35	2.90±1.36	2.81±1.45[d]
Number of relapses in the last 12 months prior to screening, n (%)	1.2±0.69	1.3±0.71	0.2±0.49[d]
Number of Gd+ T1 lesions*	1.7±4.51	1.3±3.43	0.8±2.37[d]
Total volume of T2 lesions, cm^3*	13.72±13.8	12.55±13.8	NA

* Values are represented as mean±SD
# Treatment naive patients are those who have not received a prior multiple sclerosis disease modifying therapy
[a] Values presented are for total ofatumumab exposure in the continuous group; [b] Values presented are exposure to teriflunomide in core in the switch group; [c] Values presented are for ofatumumab in extension
[d] The baseline from the extension study in the ofatumumab Switch from teriflunomide group reflects the teriflunomide treatment effect during the double-blind treatment phase in the ASCLEPIOS studies.

DISCLOSURES:

The study was supported by Novartis Pharma AG, Switzerland. The detailed author disclosures will be presented in the subsequent presentation.

Presentation format: Choose one from the following

- Platform/oral
- Poster

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Selection of the category: Choose **any one** category from the following:

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