# Longer-term Safety of Ofatumumab in Patients With Relapsing Multiple Sclerosis

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## INTRODUCTION

In the Phase 3 ASCLEPIOS I/II trials, ofatumumab treatment up to 30 months had favourable safety profile and was generally well-tolerated in relapsing multiple sclerosis (RMS) patients. Here, we aim to assess the longer-term safety and tolerability of ofatumumab treatment for up to 4 years.

## DESIGN/METHODS

Patients completing the core ASCLEPIOS I/II, APOLITOS and APLIOS trials could enter ALITHIOS, an ongoing, open-label extension study. We analysed the cumulative safety data for up to 4 years with ofatumumab (cut-off: 25-Sep-2021) in the overall (N=1969), continuous (ofatumumab in core+extension; N=1292) and newly-switched (teriflunomide core and ofatumumab extension; N=677) groups. The proportion of patients with treatment-emergent adverse events (TEAEs), serious AEs (SAEs), serious infections including opportunistic infections, and malignancies will be assessed. Laboratory parameters including neutrophils, lymphocytes, and serum immunoglobulin (Ig)G and IgM levels and association with serious infections will be analysed.

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

## RESULTS

Baseline demographics and disease characteristics are presented in **Table1**. In the previously reported data (cut-off: 29-Jan-2021; treatment for ~3.5 years), 83.8% of patients had ≥1 AEs (exposure-adjusted incidence rate/100 patient-years [EAIR], 148.7) and 9.7% had ≥1 SAEs (EAIR, 4.8) with a low incidence of serious infections (2.9%; EAIR, 1.4) and malignancies (0.6%; EAIR, 0.3). Updated cumulative clinical safety data with ofatumumab for up to 4 years will be presented at the congress.

## CONCLUSIONS

Safety findings for up to 3.5 years showed ofatumumab treatment to be well-tolerated with no new safety risks identified. This additional safety data up to 4 years will inform physicians on the longer-term safety profile of ofatumumab in RMS patients.

## TABLE 1: Baseline Demographics and Disease Characteristics

| | **Ofatumumab Continuous (N=1292)** | **Ofatumumab Newly Switched (N=677)** | | **Ofatumumab Overall (N=1969)** |
|---|---|---|---|---|
| | | **Baseline of Core Study (N=677)** | **Baseline of Extension Study (N=677)** | |
| Age, years (mean±SD) | 38.0±9.06 | 38.2±9.22 | 40.1±9.21 | 38.7±9.16 |
| Age group - n (%) | | | | |
| 18 to 30 years | 312 (24.1) | 156 (23.0) | 116 (17.1) | 428 (21.7) |
| 31 to 40 years | 438 (33.9) | 244 (36.0) | 239 (35.3) | 677 (34.4) |
| 41 to 55 years | 539 (41.7) | 277 (40.9) | 288 (42.5) | 827 (42.0) |
| > 55 years | 3 (0.2) | 0 | 34 (5.0) | 37 (1.9) |
| BMI ($kg/m^2$) | 25.61±6.16 | 25.69±5.83 | 25.61±5.85 | 25.61±6.05 |
| Female, n (%) | 889 (68.8) | 456 (67.4) | 456 (67.4) | 1345 (68.3) |
| Time since diagnosis, years (mean±SD) | 5.87±6.31 | 5.45±6.00 | 7.33±6.01 | 6.37±6.25 |
| EDSS score at baseline, (mean±SD) | 2.90±1.33 | 2.77±1.32 | 2.81±1.46 | 2.87±1.38 |
| IgG levels at baseline (mean±SD); g/L | 10.31± 2.24 | 10.35±2.09 | 10.23±2.14 | 10.28±2.21 |

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|---|---|---|---|---|
| IgM levels at baseline (mean±SD); g/L | 1.34± 0.65 | 1.36±0.74 | 1.14±0.67 | 1.27±0.66 |

EDSS, Expanded Disability Status Scale; Gd+ Gadolinium-enhancing, Nfl, neurofilament light chain; OMB, ofatumumab; SD, standard deviation
For OMB newly-switched patients, their baseline values from extension study contribute to the overall summary.

**Character count: 254/250 words** (including headings)

## 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**

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- Ageing and dementia
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- Clinical neurophysiology
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- COVID-19
- Education in neurology
- Epilepsy
- Ethics in neurology
- Headache
- Higher cortical functions
- History of neurology

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- Infectious diseases
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- Neuroimmunology
- Neuroinformatics
- Neurological manifestation of systemic diseases
- Neurology and arts
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- Spinal cord and root disorders

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