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MS and related disorders

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Body

Title

COVID-19 Outcomes and Vaccination in Ofatumumab-treated RMS Patients: ALITHIOS Trial and Post-marketing Setting

Introduction

With increasing awareness on COVID-19 and the introduction of vaccines, further evidence is required to better understand the effect of COVID-19 and vaccination in multiple sclerosis (MS) patients treated with disease-modifying therapies. Data collected since the start of the pandemic to 29-Jan-2021 on the COVID-19 outcomes in ofatumumab-treated relapsing MS (RMS) patients was previously reported. This study presents updated COVID-19 outcomes and characteristics, vaccination data, and breakthrough infections in RMS patients on ofatumumab.

Methods

Demographics, baseline characteristics, and COVID-19 incidence, seriousness, severity and outcomes were analysed from the ongoing, open-label, long-term extension Phase 3b ALITHIOS study and the post-marketing setting (Cut-off date: 25-Sep-2021). Reinfections, vaccination rates and breakthrough infections were also analysed.

Results

Overall, 245/1703 patients from the ALITHIOS study reported confirmed/suspected COVID-19. Most cases were non-serious (90.2%) and mild/moderate in severity (90.6%). Most patients recovered (98.4%) with an average duration of <20 days. Overall, 23 (9.4%) patients were hospitalised and 2 (0.8%) had fatal outcomes. No patients had COVID-19 reinfection. In total, 559 patients in the ALITHIOS study were vaccinated (fully vaccinated, 476; partially vaccinated, 74; unspecified, 9). Breakthrough infections were reported in only 1.5% (7/476) of the fully vaccinated patients of which the majority were mild to moderate and all patients recovered. Findings from the post-marketing were similar to the clinical trial results.

Conclusion

Based on the updated results, there does not appear to be an increased risk of severe or serious COVID-19 in ofatumumab-treated RMS patients. A very small number of vaccinated patients had breakthrough infections, and all recovered.

Disclosure

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

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