#0983: Effect of Ofatumumab Treatment on Disability Progression Independent of Relapse Activity in Patients With Relapsing Multiple Sclerosis

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Type

Abstract

Topic

MS and related disorders

Category

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Background and aims

Ofatumumab, the first fully human anti-CD20 monoclonal antibody with a monthly 20 mg subcutaneous (s.c.) regimen, demonstrated superior efficacy versus teriflunomide in the Phase 3 ASCLEPIOS I/II trials in relapsing multiple sclerosis (RMS) patients. Here, we present data on the treatment effect of ofatumumab versus teriflunomide on progression independent of relapse activity (PIRA).

Methods

In the ASCLEPIOS I/II pooled analysis, the risk of confirmed disability progression at 3/6 months (3mCDP/6mCDP; Expanded Disability Status Scale [EDSS] score increase of >=1.0 if baseline EDSS score <6.0, or >=0.5 if baseline EDSS score >=6.0) was evaluated in three subsets of patients: (A) without confirmed relapses during the study, (B) without confirmed relapses during the study or prior to a 3mCDP/6mCDP event, and (C) with secondary progressive multiple sclerosis diagnosis at study-entry and without confirmed relapses during the study. Hazard ratios (HRs) and p-values were calculated by a Cox-regression model adjusted for study as stratum, for treatment, region, and baseline EDSS score as covariates. An inverse probability censoring weighted (IPCW) analysis, censoring patients with confirmed relapses prior to a 3mCDP/6mCDP event, was also performed.

Results

Ofatumumab significantly reduced the risk of 3mCDP and 6mCDP versus teriflunomide in all subsets analysed, except for 6mCDP in the small Subset-C (**Table**). IPCW estimation of PIRA confirmed a risk reduction of 46.0% for 3mCDP (HR [95%CI]: 0.540 [0.396–0.738], p<0.001) and 42.5% for 6mCDP (0.575 [0.409–0.808], p=0.001) versus teriflunomide.

Disability-related outcomes	Ofatumumab 20 mg n/N	Teriflunomide 14 mg n/N	HR (95% CI)	Risk reduction	p-value
3mCDP					
Subset-A	50/793	67/661	0.587 (0.407–0.848)	41.3%	0.004
Subset-B	53/796	82/676	0.516 (0.365–0.729)	48.4%	<0.001
Subset-C	6/46	11/37	0.312 (0.114–0.859)	68.8%	0.024
6mCDP					
Subset-A	42/793	53/661	0.632 (0.421–0.947)	36.8%	0.026
Subset-B	45/796	66/674	0.551 (0.377–0.805)	44.9%	0.002
Subset-C	6/46	8/37	0.463 (0.158–1.355)	53.7%	0.160

Results of treatment comparison obtained from a Cox-regression model adjusted for study as stratum, for treatment, region, and baseline EDSS score as covariates.
Subset-A: Patients without confirmed relapses during the study; Subset-B: Patients without confirmed relapses during the study or prior to a 3mCDP/6mCDP event; Subset-C: Patients with a SPMS diagnosis at study entry and without confirmed relapses during the study
3mCDP, disability progression confirmed at 3 months; 6mCDP, disability progression confirmed at 6 months; CI, confidence interval; EDSS, Expanded Disability Status Scale; HR, hazard ratio; N, total number of patients included in the analysis; n, number of patients with the specified event; SPMS, secondary progressive multiple sclerosis

Table. Risk of 3mCDP and 6mCDP by patient subsets

Conclusion

Ofatumumab 20 mg s.c. monthly dosing regimen markedly reduced disability progression independent of relapses versus teriflunomide in RMS patients.

Disclosure

This study was funded by Novartis Pharma AG, Basel, Switzerland. A detailed disclosure from each author will be included in the oral/poster presentation. Abstract also submitted to AAN 2020; acceptance pending.

Affirmations

Authors agreement: I confirm, that all authors mentioned in the author block of this abstract have been informed about, and agreed to this submission. (I confirm)

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