European Charcot Foundation 2022

Cognitive Processing Speed at First Relapse in MS: Ozanimod vs Interferon β-1a

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Short Title: Processing Speed at Relapse in SUNBEAM

Introduction: Patients with relapsing multiple sclerosis (RMS) may experience cognitive decline during relapses.

Objectives: To determine the proportion of patients who experienced worsening cognitive processing speed (CPS) during relapse with ozanimod vs interferon β-1a (IFN) in the SUNBEAM trial and the association between baseline thalamic volume (TV) and CPS worsening during relapse.

Methods: SUNBEAM (NCT02294058) was a multicenter, randomized, double-blind trial in which patients with RMS received oral ozanimod 0.92 or 0.46 mg/d or IM IFN 30 µg/wk for ≥12 mo. The SDMT was administered at MS relapse assessments and scheduled visits. Between-treatment differences in clinically meaningful worsening (≥3 or ≥4 pt decreases) on SDMT within 7 or 30 d of first confirmed relapse in the ozanimod 0.92 mg vs IFN groups, and descriptive statistics for baseline TV in those with vs without ≥3 or ≥4 pt worsening on SDMT within 7 or 30 d were determined.

Results: Fewer patients relapsed in the ozanimod 0.92 mg group (84/447 [18.8%]) vs the IFN group (132/448 [29.5%]). Proportion with ≥3-pt worsening on SDMT within 7 d of relapse was 34.6% with ozanimod vs 47.1% with IFN (difference: -12.5% [95% CI -

26.2, 1.2]) and within 30 d was 34.1% vs 46.5% (difference: -12.3% [95% CI -25.7, 1.1]). Proportion with ≥4-pt worsening on SDMT within 7 d was 29.6% with ozanimod vs 42.9% with IFN (difference: -13.2% [95% CI -26.6, 0.1]) and within 30 d was 29.3% vs 42.5% (difference: -13.3% [95% CI -26.3, -0.2]). Mean baseline TV was similar (14.3–15.2 cm^3) among those with and without clinically meaningful worsening on SDMT within 7 or 30 d of relapse in both groups.

Conclusion: Ozanimod reduced the proportion of patients with clinically meaningful worsening of CPS within 30 d of first confirmed relapse relative to IFN.

Previously presented at: ECTRIMS, Oct 26-28, 2022, Amsterdam, Netherlands

Funding: SUNBEAM was supported by Celgene International II.

Disclosures

JD: personal compensation for consulting from Celgene, Biogen IDEC, Consortium of MS Centers, and Novartis; speaker for Sanofi Genzyme, Canadian MS Society, and EXCEMED; grant funding from Biogen IDEC, EMD Serono, Canadian MS Society, National MS Society, and Consortium of MS Centers
BB: personal fees for consulting, serving on steering committees, and speaking from Biogen, Bristol Myers Squibb-Celgene, Merck, Novartis, and Roche
DK: Biogen, Bristol Myers Squibb, Janssen; research support: Bristol Myers Squibb
JAC: personal compensation for consulting for Biogen, Bristol Myers Squibb, Convelo, Genentech, Janssen, NervGen, Novartis, and PSI; speaking for H3 Communications; and serving as an editor of *Multiple Sclerosis Journal*
XM: speaking honoraria and travel expenses for participation in scientific meetings, has been a steering committee member of clinical trials or participated in advisory boards of clinical trials in the past 3 years with Actelion, Alexion, Bayer, Biogen, Bristol Myers Squibb/Celgene, EMD Serono, EXCEMED, Genzyme, Hoffmann-La Roche, Immunic, Janssen Pharmaceuticals, MedDay, Merck, Mylan, MSIF, NervGen, NMSS, Novartis, Roche, Sanofi-Genzyme, Teva Pharmaceuticals, and TG Therapeutics
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HPH: personal fees for consulting, serving on steering committees, and speaking from Bayer Healthcare, Biogen, Celgene, GeNeuro, Genzyme, Merck, MedImmune, Novartis, Octapharma, Roche, Sanofi, and Teva