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Long-Term Effect of Siponimod on MRI Outcomes in Secondary Progressive Multiple Sclerosis: Analyses from the Expand Study up to 5 Years

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Abstract Text:

Background:

In the Phase 3 EXPAND core study, siponimod compared with placebo significantly reduced disability progression, cognitive decline, MRI measures of focal inflammation, and global and regional brain volume loss (VL) in secondary progressive multiple sclerosis (SPMS) patients.

Objectives:

To evaluate the long-term effect of siponimod on VL of whole brain, cortical grey matter (cGM), and thalamus, and changes in T2 lesion volume (T2LV) and cumulative number of new/enlarging T2 (neT2) lesions in the EXPAND extension study.

Methods:

Of 1651 patients randomized and completing EXPAND core (median 21 months), 1224 entered the 7-year, open-label extension study. Changes in MRI outcomes from EXPAND core baseline to Month 60 were compared between continuous (siponimod in core/extension) and switch (placebo in core/siponimod in extension) groups. Furthermore, within group comparisons for annualized rate of brain atrophy [ARBA], and yearly T2LV change and neT2 counts in extension versus core were assessed. Data were analyzed using non-parametric methods and models for repeated measures.

Results:

At Month 60, treatment effects on VL of whole brain (-1.62% vs -1.76%, $p<0.05$) and thalamus (-2.68% vs -3.48%, $p<0.0001$) were more pronounced in the continuous versus switch group; cGM VL was low in both groups (-1.42% vs -1.43%). T2LV change and neT2 counts were reduced in the continuous versus switch group (326 vs 870 mm^3 and 3.4 vs 9.3, both $p<0.0001$). Within-group comparison of extension versus core phase: the switch group recapitulated the pronounced reductions in VL of whole brain (58.1%), cGM (85.4%), and thalamus (58.3%), and yearly T2LV change (94.3%) and neT2 counts (72.8%) on starting siponimod (all, $p<0.0001$); low ARBA/lesion activity was maintained in the continuous siponimod group.

Conclusions:

Siponimod treatment showed sustained efficacy on MRI measures, including GM atrophy over the long-term, and benefit upon switching from placebo. Persistent differences between continuous and switch groups in measures of brain tissue integrity highlight the importance of early treatment initiation.

Title:
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Preferred Presentation Format:
Poster

Category:
Disease-modifying therapy

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Yes

Category: Disease-modifying therapy

Keywords:
Disease-modifying treatments in MS and Imaging and MS

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