

## TERIFLUNOMIDE SLOWS DOWN BRAIN VOLUME LOSS IN RELAPSING MS: A SIENA ANALYSIS OF THE TEMSO MRI DATASET

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### BACKGROUND/OBJECTIVES

Two phase 3 studies, TEMSO (NCT00134563) and TOWER (NCT00751881), showed significant effects of teriflunomide on slowing disability progression in patients with relapsing MS (RMS). In TEMSO, teriflunomide significantly reduced lesional MRI disease markers, but no significant attenuation of brain volume loss (BVL) (measured by brain parenchymal fraction) was observed. Given associations of BVL and long-term disability, blinded independent analysis of the TEMSO MRI dataset was warranted using a validated alternative methodology, SIENA (structural image evaluation using normalization of atrophy), to assess effects of teriflunomide on BVL.

### METHODS

Median annualized percentage change in brain volume from baseline was calculated (SIENA). Treatment groups were compared by rank ANCOVA, adjusted for region, age, Expanded Disability Status Scale strata, and normalized brain volume (SIENAX) at baseline.

### RESULTS

969 patients were included. Median percentage reduction from baseline in brain volume at Months 12 and 24 for placebo was 0.61 and 1.29. For teriflunomide 14mg and 7mg these reductions were 0.39 and 0.90, and 0.40 and 0.94. BVL was lower for both teriflunomide groups vs placebo at Months 12 and 24: 14mg (36.9%,  $P=0.0001$ ); 7mg (34.4%,  $P=0.0011$ ); and 30.6% ( $P=0.0001$ ) for 14mg; 27.6% ( $P=0.0019$ ) for 7mg.

### CONCLUSIONS

Teriflunomide was associated with significant reductions in BVL vs placebo over 2 years. These findings, using SIENA, an established measure of brain tissue loss, are consistent with effects of teriflunomide on delaying disability progression observed across studies in patients with RMS.

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