150 TERIFLUNOMIDE IN EARLY STAGE MS: RESULTS FROM TOPIC

Benjamin Turner,[1] Deborah Bauer,[2] Myriam Benamor,[3] Philippe Truffinet,[4] Aaron Miller[5]. [1]*Barts Health NHS Trust;* [2]*Genzyme, a Sanofi company;* [3]*Sanofi R&D;* [4]*Genzyme, a Sanofi company (France);* [5]*Icahn School of Medicine at Mount Sinai*

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Introduction Teriflunomide is a once-daily oral immunomodulator approved for relapsing–remitting multiple sclerosis (RRMS). Here we report the efficacy and safety outcomes from the TOPIC trial (NCT00622700).

Methods TOPIC was a double-blind, placebo-controlled, parallel-group study in patients with a first clinical episode consistent with MS. Patients were randomised to teriflunomide 14 mg, 7 mg or placebo. The primary endpoint was occurrence of a new clinical relapse, and the key secondary endpoint was occurrence of a new clinical relapse or MRI lesion. Safety and tolerability were also assessed.

Results Baseline characteristics were generally well balanced across groups. Teriflunomide 14mg significantly reduced the risk of a new clinical relapse by 42.6% ($p=0.0087$) and the risk of a new clinical relapse or MRI lesion by 34.9% ($p=0.0003$) versus placebo. Teriflunomide 14 mg significantly reduced total lesion volume increase from baseline at every time point and the number of gadolinium-enhancing T1 lesions per scan versus placebo. Safety observations were similar to those of TEMSO and TOWER.

Conclusions Teriflunomide demonstrated efficacy in patients with early stage MS. Together with outcomes from TEMSO and TOWER, these findings support the beneficial effect of teriflunomide across a broad range of patients and disease activity.