

Effect of Teriflunomide on Neurofilament Light Chain Levels in Children with RMS

Jens Kuhle¹, Tanuja Chitnis², Brenda Banwell³, Marc Tardieu⁴, Douglas L Arnold^{5,6}, Andreea M Rawlings⁷, Svend S Geertsen⁷, Alex L Lublin⁷, Stephane Saubadu⁸, Philippe Truffinet⁸, Ludwig Kappos¹

¹Research Center for Clinical Neuroimmunology and Neuroscience Basel (RC2NB), MS Center and Neurologic Clinic and Policlinic, Departments of Biomedicine and Clinical Research, University Hospital and University of Basel, Switzerland; ²Massachusetts General Hospital for Children, Boston, MA, USA; ³Children's Hospital of Philadelphia, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA; ⁴Hôpitaux Universitaires Paris-Sud, Paris, France; ⁵Montréal Neurological Institute, McGill University, Montréal, QC, Canada; ⁶NeuroRx Research, Montréal, QC, Canada; ⁷Sanofi, Cambridge, MA, USA; ⁸Sanofi, Chilly-Mazarin, France

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INTRODUCTION: In children and adults with MS, plasma levels of neurofilament light chain (pNfL) correlate with disease activity. Dynamics of pNfL in teriflunomide-treated children with MS have not been investigated. Here, we summarise pNfL changes in children with relapsing (RMS) receiving teriflunomide or placebo.

METHODS: TERIKIDS (NCT02201108) is a 96-week, multinational phase 3 study of RMS patients aged 10-17 years, randomised to teriflunomide (14 mg adult equivalent) or placebo, with a 96-week open-label extension (OLE) that patients could enter early in case of clinical relapse or high MRI activity. pNfL data were measured using the NF-light[®] assay and evaluated using descriptive statistics and mixed-effects model with repeated measures. Baseline for pNfL was core study Week (W)2.

RESULTS: Data in this post hoc analysis (OLE cut-off: 9 April 2021) were available for 79 patients at baseline (teriflunomide, 54; placebo, 25) and 67 at OLE W36 (teriflunomide, 46; placebo, 21). At baseline, mean age was 15.1 years, 71% were female, and treatment groups were well matched for age, sex, number of relapses in previous year, and gadolinium-enhancing lesion counts. Estimated baseline mean (95%CI) pNfL was similar between groups (teriflunomide, 18.5 [14.7-23.2] pg/mL; placebo, 19.2 [13.7-26.8] pg/mL; $P=0.86$). By W24, pNfL decreased with teriflunomide (14.5 [11.9-17.7] pg/mL) and increased with placebo (21.1 [15.5-28.5] pg/mL; $P=0.04$). By W36, pNfL decreased in both groups (teriflunomide, 14.2 [11.5-17.6] pg/mL; placebo, 16.6 [12.0-22.9] pg/mL), possibly because placebo patients experiencing relapse or high MRI activity transferred to the OLE. This interpretation is supported by an increase in mean pNfL for placebo/teriflunomide at OLE W4 relative to core study W36 (+8.4 pg/mL) versus a decrease for teriflunomide/teriflunomide (-1.8 pg/mL). At all OLE timepoints, mean pNfL levels were significantly lower for teriflunomide/teriflunomide versus placebo/teriflunomide.

CONCLUSIONS: This preliminary analysis suggests that teriflunomide is associated with decreased pNfL in children with RMS.

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