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# Reduced Grey Matter Atrophy in Patients with Relapsing Multiple Sclerosis Treated with Cladribine Tablets

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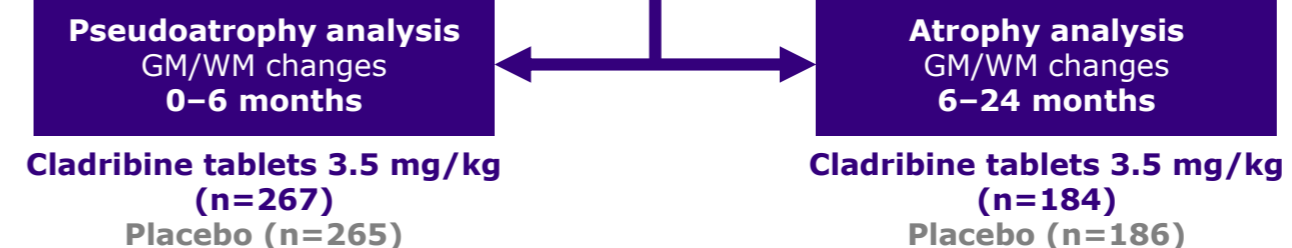


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## METHODS

**CLARITY: GM/WM atrophy study**  
Patients randomized to cladribine tablets 3.5 mg/kg or placebo for 2 years in CLARITY with images from pre-gadolinium T1-weighted magnetic resonance imaging scans evaluated using SIENA-XL software<sup>3</sup>



- Images from 0-6 months were analyzed independently of images from 6-24 months to account for possible pseudoatrophy.
- Annualized mean % changes in GM/WM volume between cladribine tablets 3.5 and placebo for 0-6 and 6-24 months over time were compared using a variance model.



## CONCLUSIONS



A reduction in grey matter volume loss was noted from 6-24 months in cladribine-treated patients versus placebo, after a period of pseudoatrophy (0-6 months).

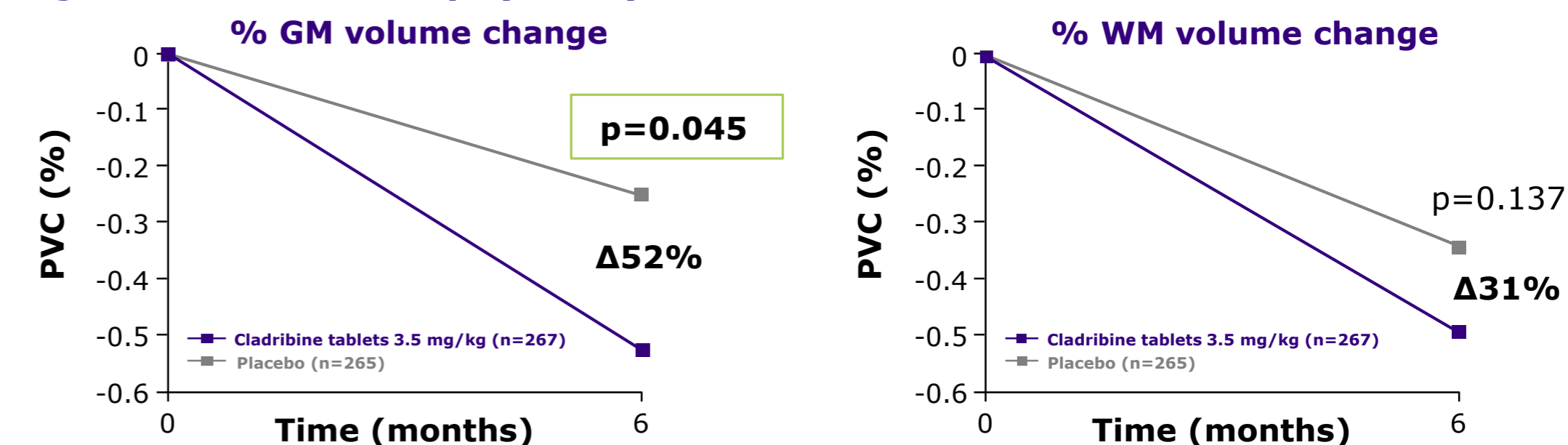


Findings suggest that cladribine tablets 3.5 mg/kg significantly reduces brain atrophy predominantly in the grey matter, an effect that may contribute to a lower risk of disability progression.



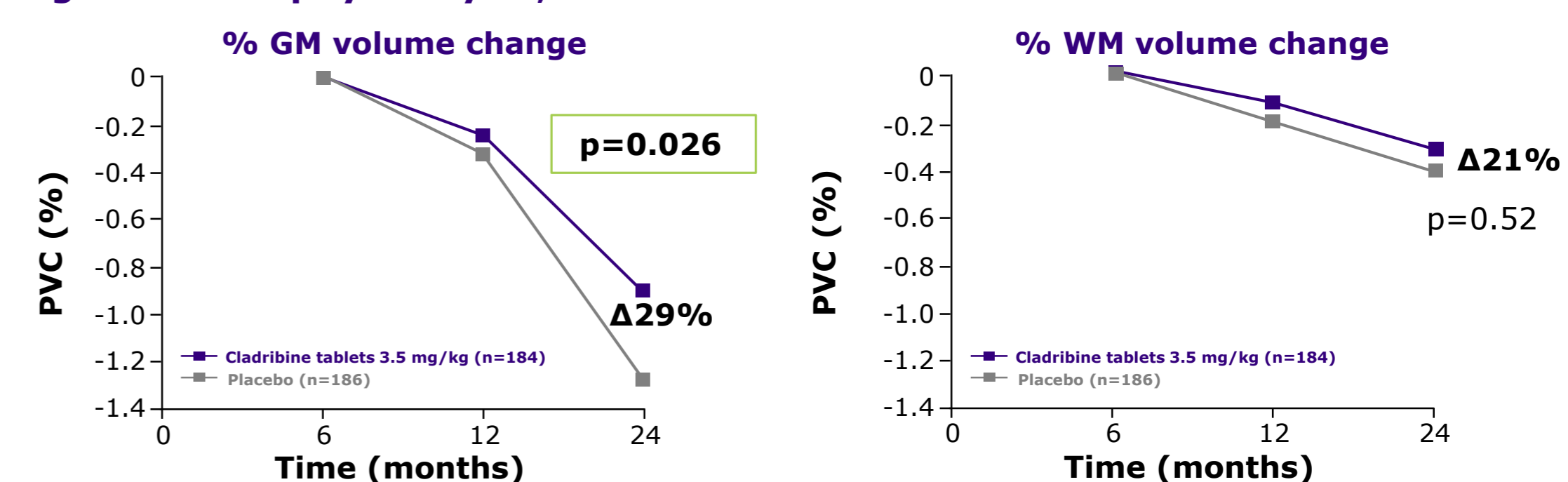
## RESULTS

**Figure 1. Pseudoatrophy analysis, 0-6 months**



Pseudoatrophy is present both in GM and WM during the first 6 months of therapy  
Significant difference in volume change between cladribine tablets 3.5 mg/kg and placebo for GM only

**Figure 2. Atrophy analysis, 6-24 months**

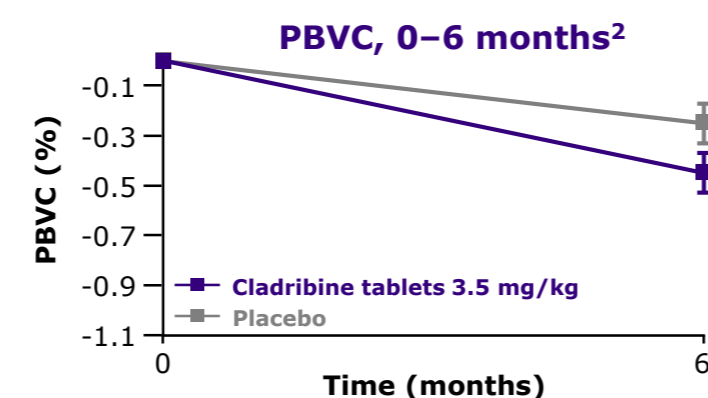


Brain volume loss from 6-24 months was reduced in patients treated with cladribine tablets 3.5 mg/kg  
Significant difference in volume change between cladribine tablets 3.5 mg/kg and placebo for GM only

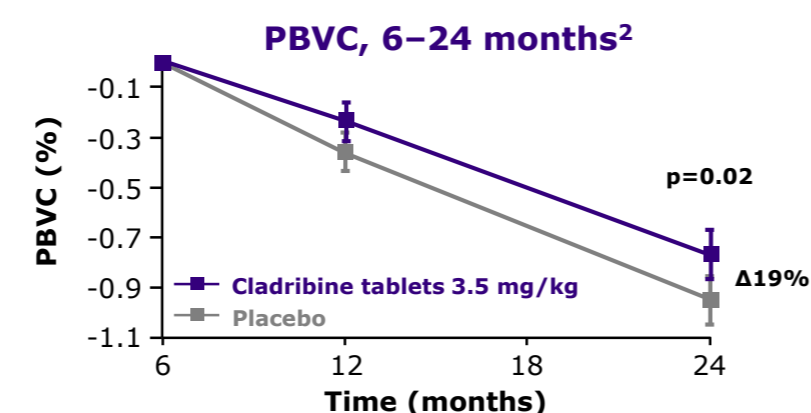


## INTRODUCTION

- Grey matter atrophy is associated with disability progression and cognitive decline in patients with MS.<sup>1</sup>
- In the **CLARITY study**, treatment with cladribine tablets decreased brain atrophy compared with placebo which was closely associated with a lower risk of disability progression.<sup>2</sup>



Pseudoatrophy<sup>1</sup>  
Anti-inflammatory effect early in the course of cladribine treatment



## OBJECTIVE

- *Post hoc* evaluation of grey matter and white matter volume changes in patients with relapsing MS randomized to cladribine tablets 3.5 mg/kg bodyweight (cumulative dose over 2 years) or placebo in the CLARITY study.

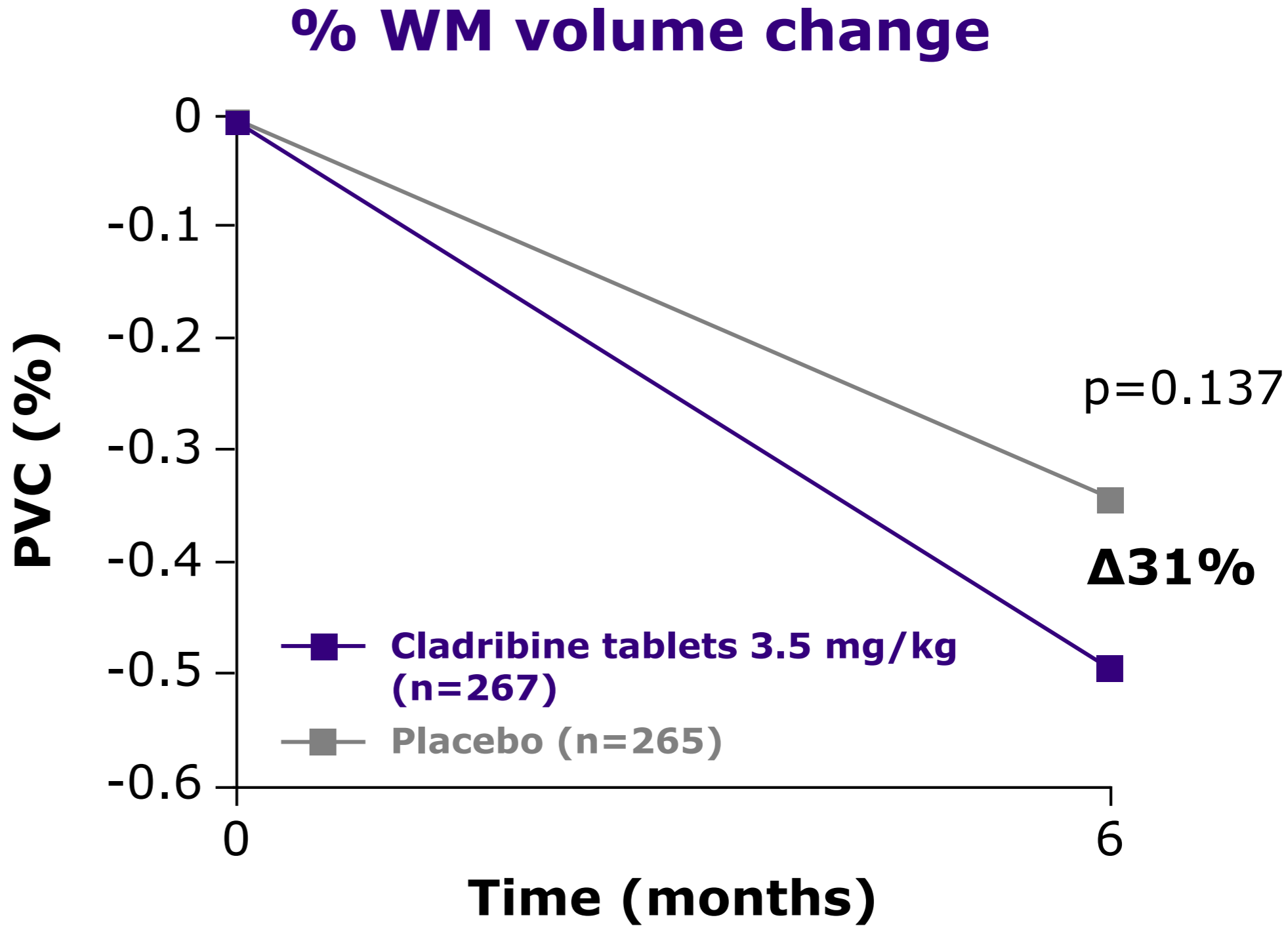
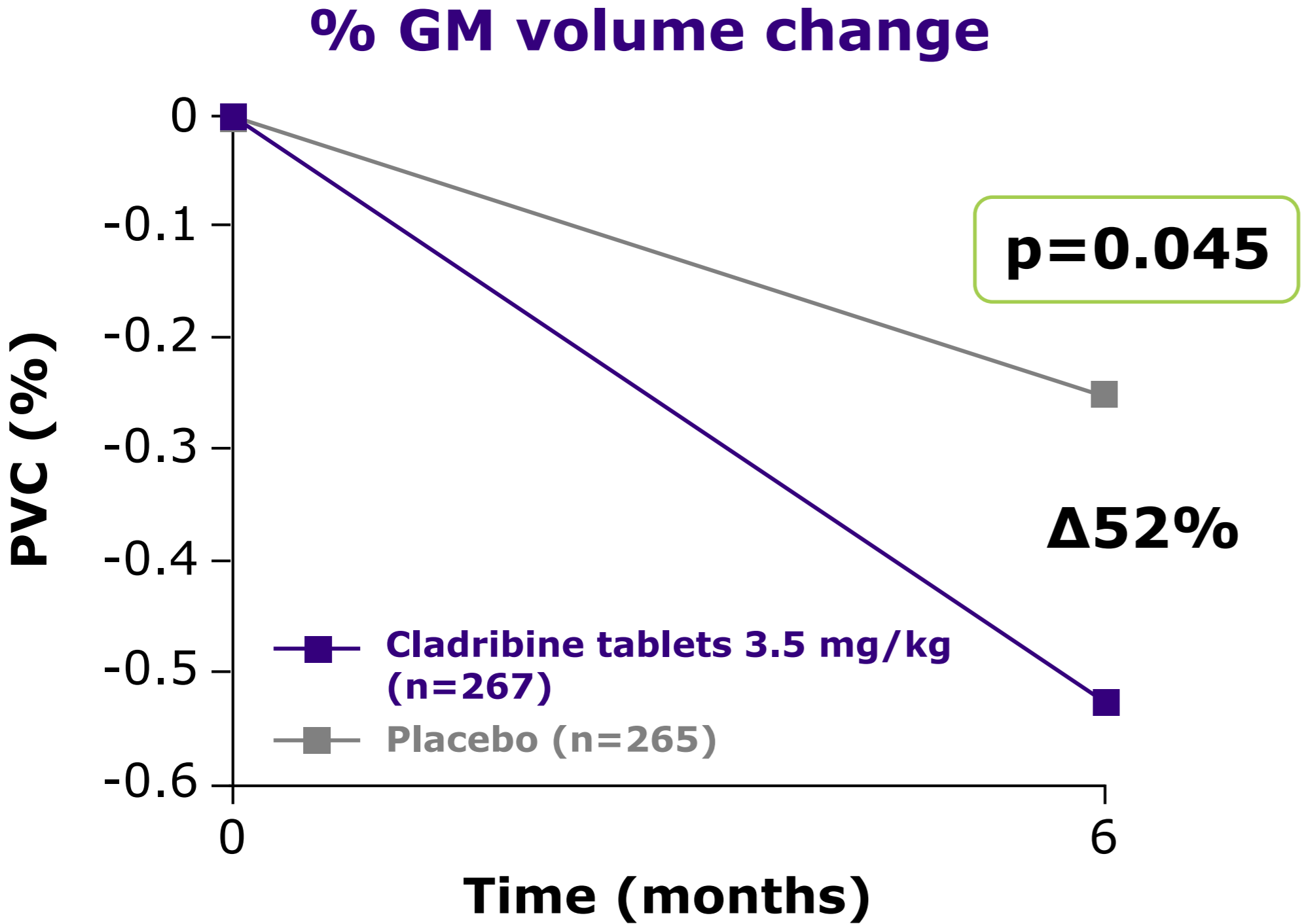
**Abbreviations:** GM, grey matter; MS, multiple sclerosis; PBVC, percentage brain volume change; PVC, percent volume change; WM, white matter


**References:** 1. De Stefano N, et al. *CNS Drugs*. 2014;28:147-156. 2. De Stefano N, et al. *Mult Scler*. 2018;24:222-226. 3. Battaglini M, et al. *Hum Brain Mapp*. 2018;39:1063-1077.

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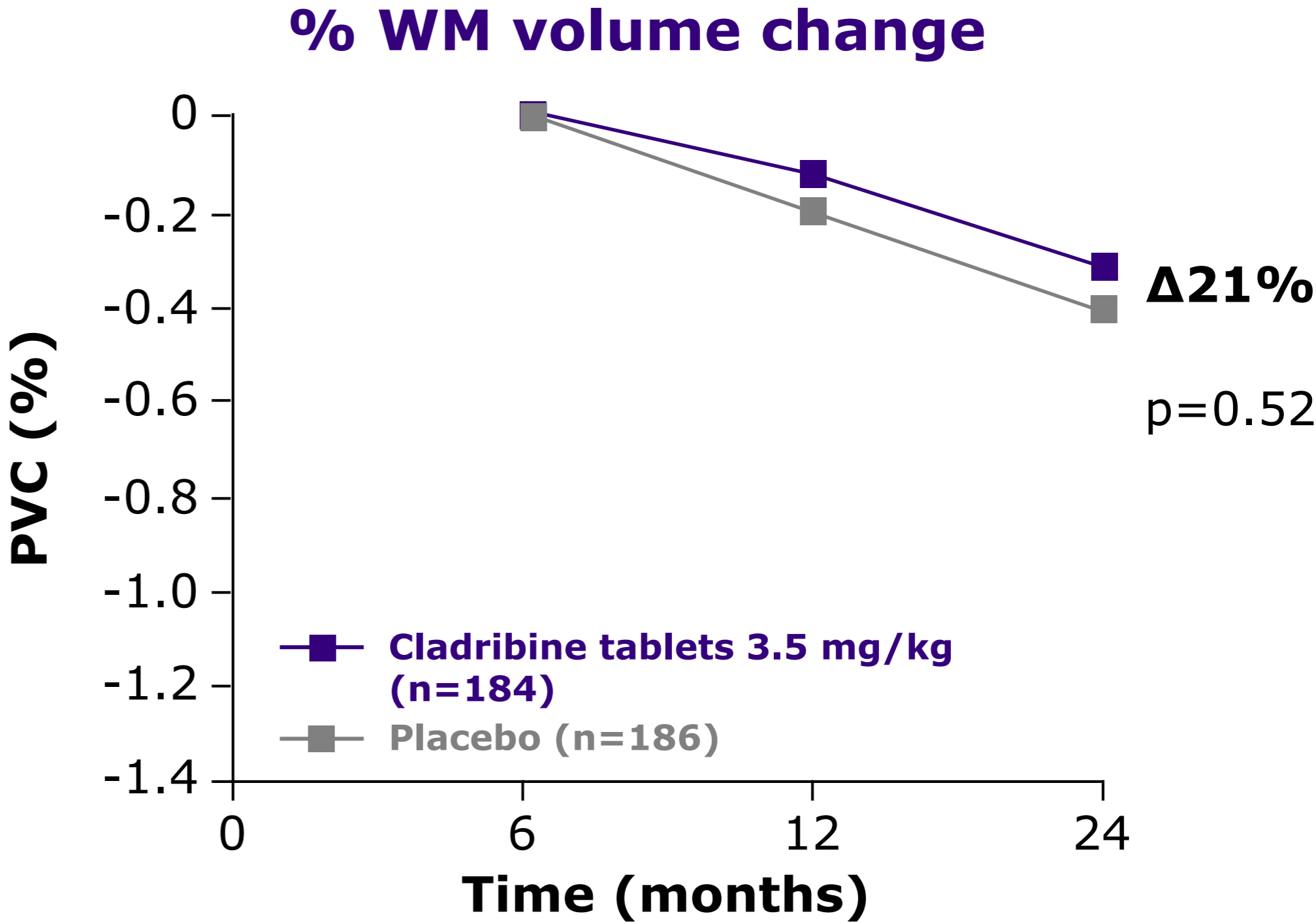
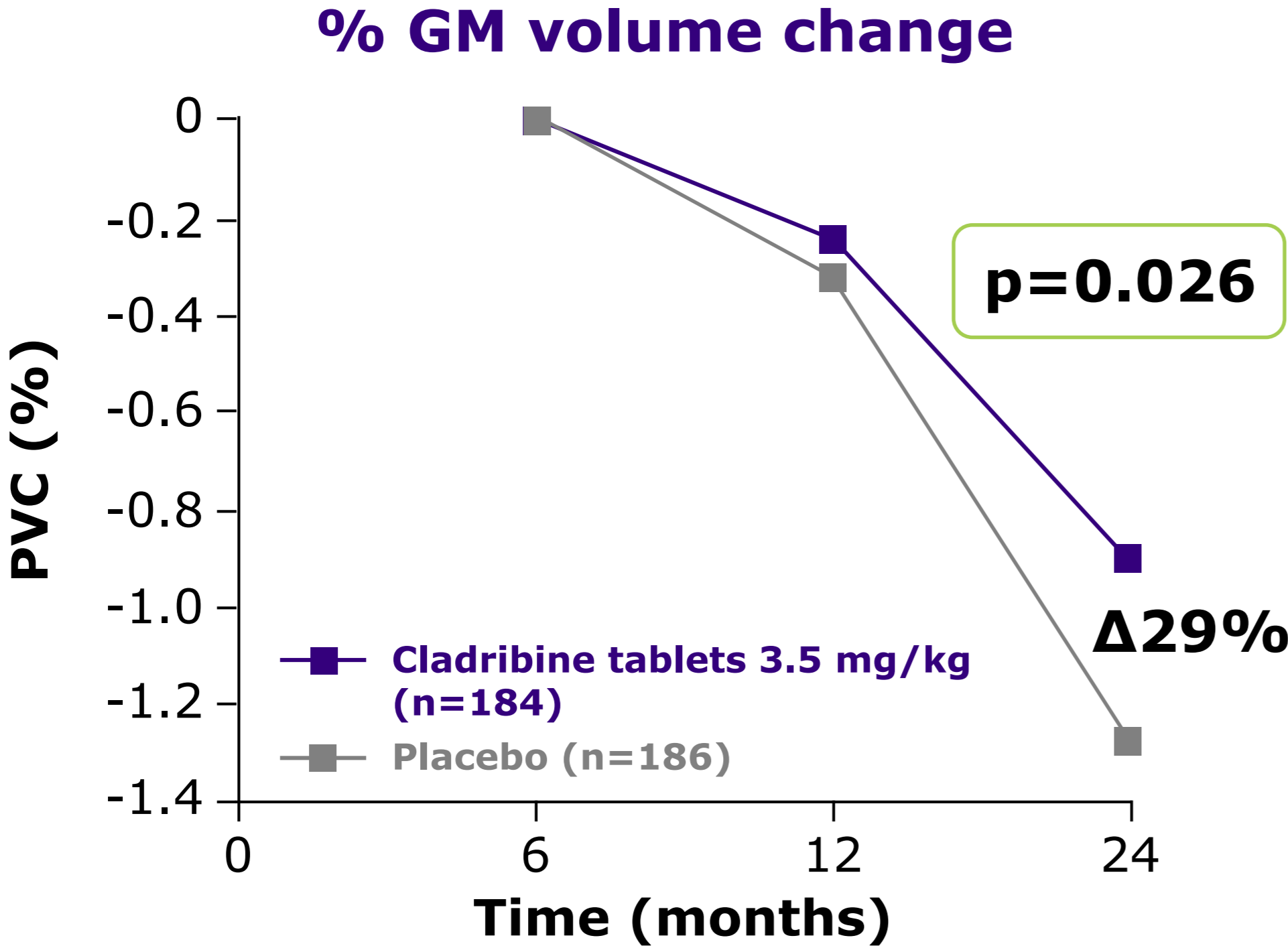
# Figure 1. Pseudoatrophy analysis, 0–6 months



 **Pseudoatrophy is present both in GM and WM during the first 6 months of therapy**  
**Significant difference in volume change between cladribine tablets 3.5 mg/kg and placebo for GM only**

**GM**, grey matter; **PVC**, percentage volume change; **WM**, white matter

# Figure 2. Atrophy analysis, 6–24 months



 **Brain volume loss from 6–24 months was reduced in patients treated with cladribine tablets 3.5 mg/kg**  
**Significant difference** in volume change between cladribine tablets 3.5 mg/kg and placebo **for GM only**

**GM**, grey matter; **PVC**, percentage volume change; **WM**, white matter