IP 169

Multicenter open-label non-interventional study (NIS) assessing the alteration of activity in amulatory patients with relapsing forms of Multiple Sclerosis (RMS) under treatment with Copaxone – Results of an interim analysis of the NIS COPTIVITY

Tjalf Ziemssen[1], Ulf Schulze-Topphoff[2], Daniel Fendji[2]

[1]*Institut und Poliklinik für Diagnostische und Interventionelle Neuroradiologie, Universitätsklinikum Carl Gustav Carus, Dresden, Deutschland*

[2]*Teva GmbH, Berlin, Deutschland*

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Background: Real-world (RW) data on effectiveness, tolerability as well as patient-reported outcomes of disease-modifying therapies (DMTs) in multiple sclerosis (MS) are missing and gaining increasing importance especially due to the rapidly changing treatment landscape in MS. Such data are not available for newer DMTs including the new formulation of Copaxone® 40mg tiw and RW evidence on effectiveness after switching from other DMTs are needed. In addition, other parameters than relapses and disability such as ability to work, participation in social life, fatigue, mental fitness also contribute to the quality of life (QoL) and are emerging endpoints in Phase IV clinical trials.
Aims: To describe the effect of Copaxone® 40mg tiw on clinical endpoints and on measures of QoL in ambulatory patients which are a) newly diagnosed, b) switching from other DMTs, and c) Copaxone® pre-treated patients.
Methods: COPTIVITY is an ongoing two-year, multicentre, non-interventional, open-label study, in ambulatory GA-treated (Copaxone® 20mg daily or Copaxone® 40mg tiw) patients recruited between Dec 2014 and March 2016. Activity endpoints were assessed in three different groups a) GA pre-treated Patients (no longer than 18 months) continuing their treatment or switching to Copaxone®, b) MS patients switching from other DTMs, and c) de-novo patients. In addition to safety, relapses and disability, fatigue (FSMC), work (WPAI-MS), QoL (EQ-5d-5L), information processing (SDMT) and treatment satisfactory (TSQM-9) were assessed. An interim analysis of patients who concluded the 12 month visit (n= 480) was conducted.
Results: Baseline characteristics: N = 1020 patients were enrolled of which 91% were RRMS and 9% CIS with a mean age of 39.3 ±11,3 and a gender distribution of 79% females and 21% males. Most of the patients were pre-treated with Copaxone® (49.6%), 34% were de-novo and 15.1 % switched from other DMTs (e.g. 66.2% interferons, 31% DMF, 6.9 FTY%, and 6.9% Aubagio). The proportion of patients receiving Cop 40mg tiw was 69.2% at baseline and increased to 82% by month 12. After one year 79.2% of patients showed no disability progression according to EDSS and 70% of the patients were relapse free. From Baseline to 12 month a significant increase of the SDMT score was observed. All other parameters were without significant changes in a cohort of n=480 patients treated with Copaxone® 20mg or 40mg tiw. Both formulations were safe and well tolerated.
Conclusion: In a real-world setting, Copaxone® is a safe and effective DMT with beneficial effect on cognitive performance and the results show that patients prefer the new 40mg tiw formulation of Copaxone® independent of their treatment history (de-novo, pre-treated with Copaxone® 20mg daily or switched from other DMTs). Ongoing analysis on the complete study cohort and subgroups (Copaxone® 20mg and 40mg tiw) will provide further evidence on clinical effectiveness and other parameters such as fatigue, cognition, ability to work, and QoL.