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OBJECTIVES: To report the effect of BG-12 (dimethyl fumarate) in reducing the number of relapses requiring intravenous (IV) steroids and multiple sclerosis (MS)-related hospitalizations from a pre-specified integrated analysis of DEFINE and CONFIRM, which was designed to estimate–more precisely–the therapeutic effect of BG-12 versus placebo.

METHODS: Eligible patients were aged 18-55 years with relapsing-remitting MS (McDonald criteria) and an Expanded Disability Status Scale score of 0-5.0. Patients who received oral BG-12 240 mg twice (BID) or three times daily (TID) or placebo were included and the integrated analysis was to be conducted only if baseline characteristics and treatment effects were similar between the studies. Numbers of relapses requiring IV steroids and MS-related hospitalizations in DEFINE and CONFIRM were assessed.

RESULTS: The integrated analysis included 769, 761, and 771 patients who received BG-12 BID, TID, and placebo, respectively. Baseline characteristics were generally similar across studies. Both BG-12 BID and TID reduced ARR versus placebo by 50% (BID; rate ratio 0.50 [95% confidence interval 0.40–0.64]) and 53% (TID; 0.47 [0.37–0.60]) in patients with ≤1 relapse in the year before study entry and 47% (BID; 0.53 [0.40–0.72]) and 41% (TID; 0.59 [0.44–0.80]) in patients with ≥2 relapses per year. BG-12 on both clinical and neuroradiological measures across a wide spectrum of RMS patients.

PN14

PROPHYLACTIC TREATMENT WITH A TARSPORTER INHIBITOR IN PATIENTS WITH RISK OF SEIZURE-RELATED T2 LESIONS AND DISABILITY PROGRESSION

OBJECTIVES: To measure the effect of tarsoptin on reducing the number of new/enlarging T2 lesions and disability progression. The pre-specified integrated analysis was conducted to assess the potential for harm for the baseline population comprised 2,301 patients while MRI evaluations were performed in a cohort of 1,046 patients. Baseline characteristics and treatment effects were generally similar across studies. Both BG-12 BID and TID reduced ARR versus placebo by 50% (BID; rate ratio 0.50 [95% confidence interval 0.40–0.64]) and 53% (TID; 0.47 [0.37–0.60]) in patients with ≤1 relapse in the year before study entry and 47% (BID; 0.53 [0.40–0.72]) and 41% (TID; 0.59 [0.44–0.80]) in patients with ≥2 relapses per year.

CONCLUSIONS: These findings further indicate consistent efficacy of BG-12 on both clinical and neuroradiological measures across a wide spectrum of RMS patients.

PN12

THE EFFICACY AND TOLERABILITY OF PERAM PANEL COMPARED TO OTHER ADJUNCTIVE RECENTLY APPROVED ANTI-EPILIEPTIC DRUGS (AEDS) FOR THE TREATMENT OF PARTIAL EPILEPSY: A SYSTEMATIC REVIEW AND BAYESIAN NETWORK META-ANALYSIS (NMA)

OBJECTIVES: To compare the clinical efficacy and tolerability of perampanel to other recently approved AEDs (lacosamide (LCM), retigabine (RTG), and eslicarbazepine (ESL)) for the adjunctive treatment of partial onset seizures or with or without secondary generalization.

METHODS: A systematic literature review was conducted to identify all RCTs of Per and selected AEDs. EMBASE, MEDLINE, and the Cochrane Central Register of Controlled Trials from 1998 to September 2011, abstracts from selected 2010 and 2011 conferences, and while the regulatory approval was on the basis of 3 RCTs, which demonstrated the efficacy and acceptable safety of perampanel relative to placebo, for the purpose of funding and health technology assessment decisions comparisons to other similar AEDs are necessary. The aim is to compare the clinical efficacy and tolerability of PER relative to other recently approved AEDs (lacosamide (LCM), retigabine (RTG), and eslicarbazepine (ESL)) for the adjunctive treatment of partial onset seizures with or without secondary generalization.

RESULTS: Twelve RCTs (3 PER, 3 LCM, 3 RTG and 3 ESL) met the inclusion criteria. The odds-ratio for three outcomes: “>50% reduction in seizure frequency”, “seizure freedom” and “withdrawal due to adverse events” were estimated using fixed- and random-effects Bayesian NMA models. RESULTS: PER, 3 LCM, 3 RTG, and ESL met the inclusion criteria. In the analysis for >50% reduction in seizure frequency, all AEDs performed significantly better than placebo with odds-ratio for PER being similar to the other comparators. Perampanel demonstrated significantly better than placebo. In the analysis for “seizure freedom”, all AEDs except LCM performed significantly better than placebo. The analysis for “withdrawal due to adverse events” showed lower odds-ratio compared to other AEDs. No significant difference in tolerability was observed in all three outcomes endpoints across studies. The other AEDs when compared against each other: 

CONCLUSIONS: Compared with other licensed adjunctive AEDs, perampanel offers similar clinical efficacy and tolerability profile.