PB10
PAINTED SELF-ASSESSMENTS IN ADVANCED PARKINSON’S DISEASE WITHIN UPDRS AND “OFF” TIME SUBGROUPS: COMPARISON OF IPX066 WITH IMMEDIATE-RELEASE CARISBOPO-LEVOPODA
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OBJECTIVES: IPX066, an extended-release capsule formulation of carisboapo-levo- poda (CD-LD), is designed to produce a rapid increase in plasma levodopa concentra-
tion, similar to immediate-release CD-LD (IR), but with sustained plasma levels, allowing dosing every 6 hours. This post hoc analysis investigated whether baseline Parkinson’s disease (PD) severity influenced the patient reported efficacy of IPX066 vs. IR in advanced PD patients. METHODS: IPX066 was evaluated in a randomized, double-blind, Phase 3 study vs. IR-LD for 13 weeks in troublesome dyskinesia after treatment with IR-LD (N = 393). Patients were stratified into subgroups of higher and lower disease severity based on median baseline “off” time (56.7 hr) and Unified Parkinson’s Disease Rating Scale (UPDRS) Parts II–III (score ≤115 vs. >115). Global impression of change (PGI) was analyzed from baseline to end of study (Fisher’s exact test) and “on” time with troublesome dyskinesia by PD diary were analyzed for each subgroup. RESULTS: IPX066 significantly improved PGI (P < 0.001) and “off” time (P < 0.001) compared with IR CD-LD in the overall randomized population. IPX066 significantly improved PGI scores compared with IR CD-LD in both higher severity subgroups (P < 0.01) and lower severity subgroups (P < 0.02). Numerical improvements from baseline in “off” time were seen with IPX066 vs. IR CD-LD in each disease sever-
ity subgroup. The improvements in “off” time were significantly greater for IPX066 vs. IR CD-LD in the higher disease severity “off” (P < 0.001) and in both the higher (P < 0.02) and lower severity (P < 0.001) UPDRS subgroups. The improvement by IPX066 compared to IR CD-LD in the lower severity “off” subgroup did not reach significance (P = 11), possibly due to a floor effect. IPX066 did not significantly worsen troublesome dyskinesia over baseline (Fisher’s exact test: P = 0.05). CONCLUSIONS: Advanced PD patients reported higher global impression of change and greater improvements in troublesome dyskinesia with IPX066 compared with IR CD-LD, regardless of disease severity subgroup.

PDNS
THE Efficacy OF Melatonin FOR PRIMARY INSOMNIA: A SYSTEMATIC REVIEW AND META-ANALYSIS
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OBJECTIVES: We performed a systematic review of randomized controlled tri-
als (RCTs) to estimate the efficacy of melatonin versus placebo or other hypnotic agents on the improvement of sleep quality and quantity in patients with primary insomnia. METHODS: We searched the published literatures in eight electronic databases, including Ovid-Medline, EMBASE, the Cochrane Library, and five Korean databases through October 2014. We included articles comparing efficacy for sleep between melatonin/placebo or other hypnotic agents and placebo. The quality of studies was evaluated by using the Cochrane’s risk of bias tool. RESULTS: A total of 28 studies were included for meta-analysis. The number of patients was derived using placebo arm data from clinical trials for each outcome, there was no clinically remarkable publication bias. We did not find any evidence of statistical heterogeneity and publication bias. CONCLUSIONS: Melatonin showed to be effective for sleep in comparison with placebo, thus can be an effective option for the treatment of insomnia. Further studies are required to conclude safety profiles, economic usefulness and tolerance of melatonin.

PDN10
COMPARISON OF CLINICAL EFFECTIVENESS OF TREATMENTS FOR PSEUDOBULBAR AFFECT (PBA) A, B RESULTS FROM A SYSTEMATIC REVIEW
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OBJECTIVES: Teriflunomide is a once-daily oral immunomodulator approved for relapsing-remitting MS. Here we report the key efficacy, safety, and post hoc analy-
ses from the randomized, placebo-controlled phase 3 trials TEMSO and TOWER (NCT00134563 and TOWER (NCT0071881)). METHODS: In TEMSO/TOWER, a total of 1088/1169 patients with relapsing MS were randomized (1:1) to once-daily teriflunomide 14 mg, teriflunomide 7 mg, or placebo. Treatment duration was 108 weeks (TEMSO) or variable, based on time of enrollment (TOWER, 48–152 weeks, ending 48 weeks after last patient randomized). Primary and key secondary endpoints were analyzed relative to placebo and in Expanded Disability Status Scale (EDSS) improvement over 30 days postrelapse. RESULTS: As measured by various relapse definitions, which may relapse-related healthcare costs and improve patients’ quality of life.

PDN11
TERIFLUNOMIDE SHOWS CONSISTENT CLINICAL EFFECTIVENESS ON SEVERE RELAPSES ACROSS TEMSO AND TOWER: 2 PHASE 3 TRIALS
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OBJECTIVES: Teriflunomide is a once-daily oral immunomodulator approved for relapsing-remitting MS. Here we report the key efficacy, safety, and post hoc analy-
ses from the randomized, placebo-controlled phase 3 trials TEMSO (NCT00134563) and TOWER (NCT0071881)). METHODS: In TEMSO/TOWER, a total of 1088/1169 patients with relapsing MS were randomized (1:1) to once-daily teriflunomide 14 mg, teriflunomide 7 mg, or placebo. Treatment duration was 108 weeks (TEMSO) or variable, based on time of enrollment (TOWER, 48–152 weeks, ending 48 weeks after last patient randomized). Primary and key secondary endpoints were analyzed relative to placebo and in Expanded Disability Status Scale (EDSS) improvement over 30 days postrelapse. RESULTS: As measured by various relapse definitions, which may not have a clinically statistically significant impact on any range of well-validated clinical and HRQoL outcomes relevant for the treatment of BBA. CONCLUSIONS: The evidence base for off-label agents used for treatment of BBA is limited, relying on small often uncontrolled studies showing small clinically relevant differences and little or no safety tracking. DMQ is the only treatment claimed for BBA that has demonstrated efficacy in well-conducted clinical trials in patients with varied neurological disorders.

PDN12
ESTIMATION OF TIME TO REACH RRMS EDSS HEALTH STATES ≥7.0 OR SPMS FOR DELAYED-RELEASE DIMETHYL FUMARATE
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OBJECTIVES: The diagnostic criteria of multifocal white matter lesions in relapsing-remitting MS, have demonstrated efficacy in clinical trials on magnetic resonance imaging (MRI) and clinical endpoints, and a clinically well-defined and diverse PBA patient population, showing statistically significant improvement in a range of well-validated clinical and HRQoL outcomes relevant for the treatment of BBA. CONCLUSIONS: The evidence base for off-label agents used for treatment of BBA is limited, relying on small often uncontrolled studies showing small clinically relevant differences and little or no safety tracking. DMQ is the only treatment claimed for BBA that has demonstrated efficacy in well-conducted clinical trials in patients with varied neurological disorders.

PDN13
NUMBER NEEDED TO TREAT ANALYSIS TO ASSESS THE COMPARATIVE EFFECTIVENESS OF TERIFLUNOMIDE AND DIMETHYL FUMARATE STUDIES IN RELAPSING MULTIPLE SCLEOROSIS
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OBJECTIVES: Teriflunomide and dimethyl fumarate (DMF), oral therapies for relapsing-remitting MS, have demonstrated efficacy in clinical trials on magnetic