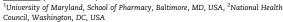
ACB score and lifestyle habits of these elders were reassessed. RESULTS: Of the 45 elders who completed the study, chlorpheniramine and other cardiac medications were found to be major contributors to the anticholinergic burden. The ACB score did not decrease at a statistically significant level after intervention, however it was found that most interventions made targeted antihistamines - suggesting suboptimal antihistamine use. The score achieved from the lifestyle questionnaire improved significantly (p < 0.05), suggesting improvement in cognitive-beneficial lifestyle knowledge and habits. **CONCLUSIONS:** The pharmacist-led intervention improved lifestyles and antihistamine-use in community-dwelling elders. Antihistamine-use might be a potential area of focus for future pharmacist-physician collaboration opportunities in the community. Future research should evaluate whether ACB score adjustment is clinically relevant in the target population.

### PND115

## A COMPARISON OF FDA AND EMA GUIDANCE ON MEDICINES FOR THE TREATMENT OF ALZHEIMER'S DISEASE

Hanna ML1, Oehrlein EM2, Perfetto EM

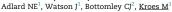


OBJECTIVES: Both the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) revised their clinical development guidelines on medicines for the treatment of Alzheimer's disease (AD) in early 2018. This study aims to compare the two guidelines to identify what may reflect regional values and preferences. **METHODS:** Draft guidance for treatment of AD by the FDA and EMA were examined and analyzed by two reviewers. A table was created to evaluate alignment between aspects of each guidance offered by two regulatory agencies. RESULTS: There is general alignment between the FDA and EMA on defining the stages of AD, diagnostic criteria, and efficacy endpoints, however, certain variations exist. The EMA guidance provides detailed recommendations on defining efficacy endpoints along the AD continuum, trial design features, and standards for outcome assessments, whereas the FDA guidance provides a brief overview of recommendations with an emphasis on endpoints for early AD clinical trials. For example, the FDA defines six stages of dementia ranging from asymptomatic with pathophysiologic changes to severe overt dementia, while the EMA adopts the IWG and NIA-AA three stages of AD (preclinical AD, prodromal/MCI due to AD, AD dementia), creating a challenge to align recommendations for stage-specific efficacy endpoints. In addition, the EMA guidance contains additional sections, including the role of biomarkers, statistical considerations, and safety evaluations, while the FDA mentioned the potential for biomarkers in asymppatients to serve as the basis for accelerated approval. CONCLUSIONS: FDA and EMA guidance for treatment of AD were similar in defining clinical benefit for early AD. The EMA guidance was more comprehensive with considerations for disease modifying treatments and outcome measures that reflect a clinically meaningful benefit for patients. FDA and EMA collaboration could be helpful in standardizing recommendations for industry in achieving clinical benefit through innovative trial design and targeted treatment effects.

NEUROLOGICAL DISORDERS - Patient-Reported Outcomes & Patient Preference

# PND116

A THREE MONTH INTERIM ANALYSIS OF FINGOLIMOD TREATMENT ADHERENCE FOR RELAPSING REMITTING MULTIPLE SCLEROSIS IN THE UK: THE PATIENT REPORTED OUTCOMES WITH FINGOLIMOD IN LOCAL EXPERIENCE (PROFILE) STUDY



<sup>1</sup>Novartis Pharmaceuticals UK Ltd, Frimley, Camberley, UK, <sup>2</sup>pH Associates (an Open

Health company), Marlow, UK

OBJECTIVES: The PROFILE study measured patient reported outcomes (PROs) in the real world in fingolimod-treated patients with relapsing remitting multiple sclerosis (RRMS); the first study to do so specifically in the UK real world setting. This abstract presents data comparing adherence to previous treatment with adherence to fingolimod at three months (M). METHODS: A prospective observational study of 144 consenting outpatients with RRMS in 14 secondary care National Health Service (NHS) centres. Eligibility: aged 18-55 years at first initiation of fingolimod ('baseline') and treated within the European product licence. Disease modifying therapy (DMT) history was collected from medical records at baseline and PROs were collected at baseline, three, six, and 12 M. A planned interim analysis of the 8-item @Morisky Medication Adherence Scale (MMAS-8-item) for 75 patients is presented for patients who were on previous treatment at baseline (excluding those on infusions, de-risking from natalizumab). RESULTS: Mean (standard deviation [SD]) MMAS-8-item score at baseline/3M: 5.8 (1.6)/7.1 (0.9); mean change: +1.4 (95% confidence interval: 1.0; 1.7). 8/35 patients reporting low adherence (MMAS-8-item score: <6) at baseline and 19/33 reporting medium adherence (MMAS-8-item score:  $\geq$ 6<8) at baseline, reported high adherence (MMAS-8-item score: 8) at 3M. At 3M, the largest proportions of patients reporting non-adherence were in the categories not taking medication yesterday: 53/75 (70.7%) compared to 17/75 (22.7%) at baseline; sometimes forgetting to take medication: 11/75 (14.7%) compared to 28/75 (37.3%) at baseline; and feeling hassled about sticking to treatment plan: 10/75 (13.3%) compared to 22/75 (29.3%) at baseline. CONCLUSIONS: Overall, patients reported improved adherence after three months of fingolimod therapy compared to baseline. In particular, notable improvements in adherence levels from medium or low at baseline, to high at 3M were observed. Therefore, it will be of interest to evaluate patients' responses to MMAS-8-item assessment in the longer term.

PHYSICIAN REPORTED ADHERENCE IN MS PATIENTS TREATED WITH INJECTABLE PLATFORM THERAPIES VERSUS DELAYED-RELEASE DIMETHYL FUMARATE: FINDINGS FROM A REAL-WORLD CROSS-SECTIONAL STUDY



Rock M<sup>1</sup>, Pike J<sup>2</sup>, Jones E<sup>2</sup>, Husbands J<sup>2</sup>, Golden K<sup>2</sup>, Gasik A<sup>1</sup>

<sup>1</sup>Biogen, Inc, Cambridge, MA, USA, <sup>2</sup>Adelphi Real World, Manchester, UK

OBJECTIVES: With more than 5 years of real-world physician experience, there is now an opportunity to better understand adherence and factors related to adherence in relapsing-remitting multiple sclerosis (RRMS) patients receiving delayed-release dimethyl fumarate (DMF). This study aims to compare physicianevaluated patient adherence in patients treated with DMF compared to compared to those receiving interferon beta-1a/1b, peginterferon beta-1a or glatiramer acetate (ABCREP). METHODS: RRMS patients receiving dimethyl fumarate or ABCREP therapies for at least 12 months were identified from the Adelphi MS Disease Specific Programme, a cross-sectional study of MS patients globally (U.S.A, U.K, Spain, Italy, France and Germany) between 2014 and 2018. Treatment effects were estimated, after propensity score matching on age, gender, EDSS, and number of prior MS therapies to create balanced treatment groups. Physician-reported patient response (efficacy) and adherence were compared between DMF and ABCREPs. RESULTS: For DMF relative to ABCREP, physicians were more likely to report patients responding very well to treatment (52.42% [N=559] vs 43.23% [N=3258], p=0.002) and adhering very well to treatment (67.07% [N=580] vs 53.74% [N=3271], p-0.002) and antering very work of treatment (0.50 % [N-363] vs 3.7 x [N-263] vs 9.7 y [N-363] vs 13.92% [N-3138], not choice of therapy with DMF vs ABCREP (27.07% [N-543] vs 13.92% [N-3138], p<0.001) and were less likely to report "improved compliance" as a desired therapy improvement with DMF vs ABCREP (2.41% [N=540] vs 5.59% [N=3009], p=0.013). CONCLUSIONS: The data from this real-world cross-sectional study suggest greater real-world adherence for DMF compared to ABCREPs in patients with RRMS. Further studies are required to establish the clinical benefits associated with the improved adherence reported in patients treated with DMF.

### PERCEPTIONS AND NEEDS OF PATIENTS WITH MIGRAINE IN GREECE: A FOCUS GROUP STUDY



Ouzounidou E, Katsara M, Kalogeropoulou M

Novartis Hellas SACI, Metamorphosis, Athens, Greece

**OBJECTIVES:** The aim of this study was to explore the perceptions, experiences and needs of a group of patients suffering from high frequent episodic (HF-EM) and chronic migraine (CM) in Greece. METHODS: In this qualitative study, data were collected through discussions in three focus groups. Participants were 15 patients in total (consent obtained) who had been experiencing HF-EM migraine (8-14 headache days within a month) and CM (≥15 headache days within a month) according to the International Classification of Headache Disorders (third edition, beta version). Group discussions focused on five domains: 1) burden of migraine (symptoms, family implications, social and professional life), 2) awareness and understanding by others, 3) knowledge of the disease, 4) issues related to disease management and 5) unmet needs. Thematic analysis was performed following appropriate guidelines for qualitative research. RESULTS: Five main themes describing the significance of suffering emerged: a) pain, as described by frequent migraine patients, is very intense while chronic patients report that pain feels life threatening; b) migraine has strong impact on family, social and professional life, c) limited understanding and awareness for what migraine really means for the public, d) migraine patients are overall disappointed by both their condition and other medication (cannot really offer them relief, or relief is too slight). Main challenges include the duration per migraine episode, intense pain symptoms, disability to function in family, social and professional life and lack of efficacy of available treatments. CONCLUSIONS: Migraine is a chronic impediment for patient's life. It radically changes quality of life bringing major implications in personal, social, professional and family levels, especially for chronic patients. Qualitative research offers insight into the way patients with migraine experience their disease and it may be helpful for physicians to establish a more fruitful relationship with these patients.

## PND119

### SURVEY ANALYSIS OF TREATMENT WITH INTERFERON BETA 1A IN BRAZIL AMONG MS PATIENTS PARTICIPATING IN A PATIENT SUPPORT PROGRAM (PSP)



Biglia LV, Conceição VB, Araújo RV

Merck, São Paulo, Brazil

OBJECTIVES: Interferon beta-1a is indicated for patients with relapsing forms of Multiple Sclerosis (MS) and usually used as first line therapy in the Brazilian public health system. The objective of this study was to assess patient satisfaction with the patient support program using a survey with MS patients receiving interferon beta-1a. METHODS: A questionnaire consisting of 20 objective questions was developed by the Merck PSP Team and sent to patients recently using interferon beta 1a participating in the PSP. An online survey was sent to 965 prospective participants. PSP specific information was measured including: time of enrollment in the PSP, quality of the online visits, assessment of advantages of the program, clarity of information provided online, frequency of contact with the PSP, and the level of satisfaction with the support that was provided. **RESULTS:** Between November 2017 and April 2018, 550 responses were recorded. The majority of the patients originated from the Southeast Region (60.9%) and 71% were female. 41.8% reported that never had difficulty to access the medication, 58.3% were enrolled in the program for more than 24 months, 50.5% classified web visit as optimal and availability/convenience were cited as the main benefits of this kind of visit. About 80% of the patients were very satisfied with the quality of the service and believed