

scriptive statistics were reported for psychiatrists' sociodemographic and professional characteristics. Part-worth utilities were estimated using random effects logit models, and relative importance values were calculated for the attributes. RESULTS: Complete data were available from 478 psychiatrists; their mean age was 52.1 (±9.4 SD) years, and the majority were male (n=326; 68.2%) and Caucasian (n=354; 74.1%). The psychiatrists had a mean of 19.0 (±9.1 SD) years' experience practicing psychiatry. Across all patient profiles, the efficacy attribute consistently had the highest relative importance (RI): 54.93%. Mode of administration (RI=13.51%) and formulary access (RI=11.33%) also contributed notably to the psychiatrists' medication preferences. Other attributes were of more minor importance, each with RI values <10%, including onset of action (RI=6.95%), dosing frequency (RI: oral=6.23%; injection=0.94%), safety (RI=4.30%), and side effects (RI=1.80%). The RI of medication attributes showed some differences across patient profiles; mode of administration increased in importance for both types of nonadherent patients, while formulary access and safety decreased in importance. CONCLUSIONS: The results of the DCE suggest that efficacy is the most important factor for psychiatrists' making medication decisions regarding the treatment of patients with schizophrenia. The RI of efficacy does not vary by patient profile; however, the RI of other attributes tends to vary depending on the profile of the patient being treated.

# ATTRIBUTES ASSOCIATED WITH A PREFERENCE FOR MONTHLY INJECTABLE THERAPY IN PATIENTS WITH SCHIZOPHRENIA

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OBJECTIVES: Identify attributes of patients with schizophrenia taking oral antipsychotics who state preference for monthly injectable antipsychotic therapy. METHODS: From a 2007-2008 survey of patients self-reporting a schizophrenia diagnosis (N=1083), respondents currently using oral antipsychotics but not injectables (N=984) were classified as preferring monthly injectable antipsychotic therapy if they answered "very likely" or "extremely likely" on a 5-point Likert scale to, "If you could receive your medication once a month as an injection, instead of having to take daily tablets or liquids, how likely would you be to choose the injection?" (N=268). The comparator group consisted of those who answered "not at all likely" or "somewhat likely" (N=485). Attributes were included in a single logistic regression model with the dependent variable indicated by the preference for monthly injectable antipsychotic therapy. Independent variables included demographics, attitudes toward disease management, previous medication and health care resource use, and self-reported adherence, as measured by the Morisky Medication Adherence Scale (MMAS). RESULTS: Current oral antipsychotic users classified as having low adherence (MMAS=3 or 4) were 1.7 times more likely to prefer monthly injectable antipsychotic therapy (p=0.03) than those more adherent. Respondents aged 35-54 years were 1.8 times more likely to prefer monthly injectable antipsychotic therapy than respondents  $\geq$ 55 years (p=0.03). Respondents who stated psychiatric medication was a "very important" or "extremely important" aspect of their life were 2.0 times more likely to prefer monthly injectable antipsychotic therapy (p=0.01) than those attaching less importance to their medication. CONCLUSIONS: In this survey of patients with schizophrenia, those who viewed their psychiatric medication as important and those who reported lower adherence were more likely to prefer once-monthly injectable antipsychotic therapy. These insights into patient attitudes and preferences can help mental health care professionals effectively engage in shared decision making with their patients. Support: Janssen Scientific Affairs, LLC.

# LEVOMILNACIPRAN IN THE TREATMENT OF MAJOR DEPRESSIVE DISORDER: FUNCTIONAL HEALTH AND WELL-BEING EFFICACY RESULTS FROM A PHASE III CLINICAL TRIAL

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OBJECTIVES: Levomilnacipran (1S, 2R-milnacipran) is a potent and selective serotonin and norepinephrine reuptake inhibitor (SNRI) in clinical development for the treatment of major depressive disorder (MDD). Primary and post hoc analyses were conducted on data from a positive Phase III trial (NCT00969709) to evaluate the functional health and well being of patients with MDD treated with sustained released (SR) levomilnacipran. METHODS: A double-blind, multicenter, parallelgroup, placebo-controlled, fixed-dose study in patients aged 18-65 years who met DSM-IV-TR criteria for MDD and Montgomery-Asberg Depression Rating Scale-Clinician Rated (MADRS-CR) score ≥30. Study comprised a 1-week single-blind, placebo lead-in, 8-week double-blind treatment, and 2-week double-blind downtaper. Patients were randomized to placebo (n=175) or once-daily levomilnacipran (n=529) 40 mg, 80 mg, or 120 mg (titrated-up from an initial dose of 20 mg). Functional health and well being were measured using change from baseline to Week 8 on the SF-36v2 acute (1-week recall) health survey. Individual health dimensions, and physical (PCS) and mental (MCS) component summary scores were compared for levomilnacipran and placebo (ITT population) using an ANCOVA model. RESULTS: Patients in both groups had deficits in mental-health (baseline MCS scores: (placebo, 17.2±9.2; levomilnacipran, 18.2±8.5); baseline PCS scores (PBO: 52.6±11.1; LVM: 51.1±11.1) were slightly higher than the population norm. Following 8 weeks of treatment, levomilnacipran patients versus placebo demonstrated significantly greater improvement in MCS (LSMD=4.4 $\pm$ 1.36; p=.0013) and on several individual dimensions (General Health [2.3 $\pm$ 0.69; p=.0007], Vitality [2.4 $\pm$ 1.05,

p=.0228], Social Functioning [3.1 $\pm$ 1.17; p=.0086], Role Emotional [3.1 $\pm$ 1.20; p=.0097], Mental Health [4.3 $\pm$ 1.16; p=.0003]. Nonsignificant PCS [-0.2 $\pm$ 0.74; p=.8386] and other dimension score changes were noted. CONCLUSIONS: Levomilnacipran patients experienced statistically significant and clinically meaningful improvements in functional health and well being as measured by the SF-36 MCS and associated individual dimensions. Nonsignificant changes were noted for the PCS and associated individual dimensions. Supported by funding from Forest Laboratories, Inc.

### PMH53

### MEASURING REAL WORLD OUTCOMES BY INCORPORATING PRO DATA COLLECTION INTO PATIENT ACCESS SUPPORT PROGRAMS

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OBJECTIVES: The current focus on the use of real world data in evaluating outcomes, drug value and in establishing payer coverage policies requires that data be collected post regulatory approval. The costs involved in formal late phase commitments and the challenge of getting health care providers to participate in data collection programs like registries can prove overly burdensome and rate limiting. The objective of this study is to determine if PRO measures can be incorporated into patient support programs to collect data that can demonstrate value and be presented to payers. METHODS: Many product sponsors establish a no cost and toll free program to support patients navigate their insurance benefits and obtain access to prescribe therapy. A total of 2000 opioid addicted patients were divided into 2 groups; 1000 patients were not aligned with clinical care support to monitor patient reported outcomes and 1000 that reported outcomes data into the patient support program. **RESULTS:** Patients who received support services that allowed for the collection of PRO's stayed on treatment longer than those who did not have access to report outcomes. Patients in the reporting arm stayed on therapy on average three months longer than the patients who did not report outcomes. Patients who stayed on therapy longer did not cost payers as much as those who came off of therapy sooner. CONCLUSIONS: Product sponsor patient support programs can serve as a valuable tool to support the reporting and collecting of PRO data. Such programs can contain an opt-in procedure to allow patients access to PRO tools that can help manage their disease and track treatment outcomes. Such data can then be analyzed and reported on to demonstrate product value and cost effectiveness through Budget Impact Modeling (BIM) comparing the cost of care of those who do not track PRO data vs. those who do not

## PMH54

### USING LONGITUDINAL DATA TO EXPLAIN THE IMPACT OF PAIN ON DEPRESSION FOR GENERAL POPULATION

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**OBJECTIVES:** The goal of this study was to examine the impact of physical pain on depression using longitudinal survey data for general population in the United States. METHODS: This work employed two rounds of Medical Expenditure Panel Survey (MEPS) from years 2008 and 2009. Depression was measured by frequency of feeling depressed over the last 2 weeks, scaled by 0-not at all, 1-several days, 2more than half the days, and 3-nearly every day. Physical pain was measured by severity of pain scaled by 1-not at all, 2-a little bit, 3- moderately, 4-quite a bit, and 5-extremely. People older than 18, who had reported severity of depressed mood and recent physical pain, marriage status, family size, and highest education degrees were included in the study. Only round 2 and round 4 of the survey were used since pain questions were only asked in these two rounds. The final panel contained 21,257 observations, among which 46.32% and 45.34% reported pain limited normal work in round 2 and round 4 respectively; 28.25% and 27.26% documented  $depressed\ mood\ in\ round\ 2\ and\ 4\ respectively.\ Ordinary\ Least\ Squares\ (OLS), Linear$ Mixed Effect Model (LME), generalized linear model (GLM) were used to examine the impact of pain on depression. RESULTS: Compared with GLM and LME, the OLS estimates were shown upward biased. GLM and LME both suggested that individuals whose physical pain deteriorated to the next level from round 2 to round 4 would present a 0.16 (p<0.0001) more depressed mood (based on 0-3 scale) on average. Individuals perceived better health status, were older, richer, married, and employed were less depressed. CONCLUSIONS: This work utilized a national representative longitudinal data to examine the impact of physical pain on depression. Severity of pain and some individual characteristics were found significantly affecting the severity of depression.

### RACIAL AND ETHNIC DIFFERENCES IN ADHD IN YOUNG AND ADOLESCENT CHILDREN: PARENTAL REPORTS IN THE MEDICAL EXPENDITURE PANEL SURVEY 2008

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OBJECTIVES: Attention-deficit/hyperactivity disorder (ADHD) is the most common neurobehavioral disorder characterized by developmentally inappropriate levels of inattention and hyperactivity. Previous literature suggests that, racial and ethnic disparities continue to exist for several medical conditions. Some studies have shown that such differences reduce when difference in family income, health insurance and such sociodemographic factors are taken into account. But, it has been also documented that such differences may accentuate for specific type of disorder. Aim of this study was to determine any racial and ethnic differences and weather such differences can be explained by child's other health condition and sociodemographic characteristics. METHODS: A nationally representative sample