treatment through time using repeated measures ANCOVA. **RESULTS:** The SIS was found to meet psychometric standards for a valid questionnaire in a GAD population. The efficacy analysis found four domains (Daily Activities, Emotional Impact, Energy/Fatigue and Satisfaction with Sleep) consistently demonstrated significantly greater improvements in the zolpidem tartrate extended-release group at each timepoint. A quick onset of treatment effect was evident in all domains of the SIS by Week 2, with all domains statistically significantly demonstrating greater improvement than placebo. Longitudinal analyses found all SIS domains to be statistically significantly superior to placebo. **CONCLUSION:** The SIS adequately meets the criteria for a validated measure to be used in GAD. The SIS was responsive to treatment effects in this clinical trial and able to demonstrate improvements in patient reported outcomes, favoring zolpidem tartrate extended-release.

PMH59

LINGUISTIC VALIDATION OF THE HADS FOR USE IN INTERNATIONAL STUDIES

Grataloup G[1], Ingham M[2], Caleo S[3], Coffey L[4]

[1]Mapi Research Institute, Lyon, Rhone, France, [2]Johnson and Johnson, Beerse, Belgium, [3]Janssen Pharmaceutica N.V, Beerse, Belgium, [4]NferNelson Publishing Company Ltd, London, UK

OBJECTIVES: Prior to use in an international study, the Hospital Anxiety and Depression Scale (HADS) underwent linguistic validation in 30 languages. The original scale was developed in UK English to detect states of anxiety and depression in and outside hospital and also community settings. A rigorous methodology was required to ensure conceptual equivalence and cultural relevance across different languages. **METHODS:** The translation process was conducted by a specialist in each target country using the following standardized methodology: 1) two forward translations by professional translators who were native speakers of the target language and fluent in English; 2) comparison and reconciliation of the translations by the specialist in the target country; 3) backward translation by a native English speaker; 4) comparison of source and backward version; and 5) review by the developer. The linguistic validation methodology for some languages deviated slightly from what is described above, as a translation already existed; the translation process started at the backward translation step on the existing version. **RESULTS:** The translation process revealed linguistic and conceptual challenges. Translating idiomatic expressions often required paraphrasing to convey the intended meaning whenever a literal equivalent was not conceptually equivalent and culturally relevant. In addition, while in most language versions it was possible to retain the same tense as in the original instrument without alteration of meaning in a few translations it proved necessary to use a different tense to achieve clarity and equivalence of concept. **CONCLUSION:** The language versions of the HADS were established according to a rigorous translation methodology. The process aims to ensure conceptual equivalence across different language versions to facilitate international comparison and pooling of data. The linguistic validation process as a whole supports the advantage of integrating international feedback on concepts and wording before a questionnaire is finalized.

PMH60

A PHARMACOECONOMIC COMPARISON OF ESCITALOPRAM AND DULOXETINE IN TREATMENT OF MAJOR DEPRESSIVE DISORDER (MDD) IN THE UNITED KINGDOM

Wade AG[1], Fernandez JL[2], François C[3], Hansen K[3], Despiegel N[3], Danchenko N[3]

[1]CPS Research, Glasgow, UK, [2]London School of Economics, London, UK, [3]H. Lundbeck A/S, Paris, France

OBJECTIVES: To evaluate cost-effectiveness of escitalopram vs. duloxetine in MDD and to identify key drivers of costs in treatment of depression with escitalopram and duloxetine. **METHODS:** An economic evaluation was conducted alongside a double-blind, randomized study (escitalopram 20 mg/day and duloxetine 60 mg/day) in outpatients with MDD, aged 18–65 years, with Montgomery Asberg Depression Rating Scale (MADRS) $\geq$26 and Clinical Global Impression Severity (CGI-S) $\geq$4, and with reported baseline duration of depressive episode of 12 weeks-1 year. The main cost-effectiveness (CEA) analysis was conducted on the full analysis set (FAS), with all patients having $\geq$1 valid post-baseline health economic assessment. Additional analyses were conducted on completers set (CS) with complete follow-up data. Outcomes included Sheehan Disability Scale (SDS), MADRS total score, treatment response (MADRS decrease $\geq$50%) and remission (MADRS$\leq$12), and health care resource use and absenteeism from work evaluated by Health Economic Assessment. Unit costs of health care services were obtained from UK published standard sources. **RESULTS:** In the main CEA analysis on FAS, escitalopram appears to be more effective on the SDS scale (95% CI 0.10–3.74) and less costly than duloxetine (95% CI $\leq$−1.544 to −247). In additional analyses on CS, patients on escitalopram had 49% lower total cost compared to duloxetine (p = 0.002), with sick leave contributing >73% of the total disease cost. Escitalopram was associated with 58% shorter sick leave duration compared to duloxetine (p < 0.001). Patients with treatment response had 46% shorter sick leave (p = 0.008), and those achieving remission, sick leave was 53% shorter (0.002). **CONCLUSION:** Escitalopram dominates duloxetine on the SDS scale, and is associated with significant cost savings compared to duloxetine. Treatment with escitalopram may reduce sick leaves duration through improved treatment response, and result in cost savings compared to duloxetine. The results are in line with other economic studies showing cost-saving with escitalopram compared to venlafaxine, another SNRI.

RESPIRATORY DISORDERS—Clinical Outcomes Studies

PRS1

ACUTE EFFECTS OF SILDENAFIL ON ECHOCARDIOGRAGHIC PARAMETERS IN PATIENTS WITH PRIMARY PULMONARY HYPERTENSION

Behzad Nia N, Najafi Zadeh K, Sharif Kashani B, Shahabi P

National Research Institute of Tuberclusis and Lung Disease (N. R. I. T. L. D), Tehran, Iran

OBJECTIVES: Primary pulmonary hypertension (PPH) is a disorder with limited treatment options. Sildenafil, an oral phosphodiestrase type-5 (PD-5) inhibitor and a pulmonary vasodilator, is likely to be beneficial in patients with primary pulmonary hypertension,. we hypothesized that a single dose of Sildenafil could acutely reduce peak pulmonary artery pressure and improve echocardiographic diameters of right heart. **METHODS:** We studied 12 consecutive patients with PPH (10 patients with New York Heart Association functional class [222], and 2 patients with functional class[22]). After initial echocardiographic evaluation, a 100 mg oral single dose of Sildenafil was added to previous