PWE-074

RESPONSE OF CHRONIC CONSTIPATION SYMPTOMS TO PRUCALOPRIDE TREATMENT AND RELATIONSHIP WITH PATIENT SATISFACTION

doi:10.1136/gut.2011.239301.337

R Kerstens,^{1,*} L Vandeplassche,¹ D Dubois,² L Wouters³ ¹MOVETIS NV, Turnhout, Belgium; ²Patient Value Solutions, Huldenberg, Belgium; ³I-BioStat, Hasselt University, Diepenbeek, Belgium

Introduction Prucalopride (PRU) is a selective 5-HT₄ agonist, effective and approved in EU for treatment of chronic constipation (CC) in females in whom laxatives do not provide adequate relief. The aim of this study was to assess the meaningfulness of changes in constipation symptoms and patient satisfaction after 4 weeks of treatment with placebo, PRU 2 mg or 4 mg. In addition, the relationships between changes in symptom scores and patient satisfaction were explored.

Methods Symptoms of CC were assessed in 1552 female subjects of 3 identical pivotal trials. Subjects were selected if treated for at least 21 days and with data at baseline (BL) and 4 weeks of treatment. Symptom severity was evaluated by the Patient Assessment of Constipation Symptoms (PAC-SYM) questionnaire, a 12-item self-report instrument with abdominal (4 items), rectal (3 items) and stool (5 items) symptom subscales. Patient satisfaction with bowel habit and treatment was evaluated by the 5-item subscale of the Patient Assessment of Constipation Quality of Life questionnaire (PAC-QOL).

The meaningfulness of changes in the PAC-SYM items and patient satisfaction was assessed by the effect size (ES), that is, mean change from BL divided by the SD of the BL value. The relationship between changes after treatment with PRU in

PAC-SYM items and patient satisfaction was evaluated using partial least squares path modelling (PLSPM).

Results At BL the mean symptom severity score was 'moderate' for abdominal symptoms, 'severe' for stool symptoms and 'mild' for rectal symptoms. Treatment with PRU 2–4 mg resulted in a substantial relief of all symptoms with ES varying from moderate (ES: 0.5–0.8) to large (ES>0.8) and with the largest ES for the abdominal bloating and discomfort symptoms for both doses of PRU. Analysis of the 3 subscales showed that the ES of PRU were large (>0.8) for both the abdominal and stool symptoms. Comparison between placebo and PRU of the cumulative distributions of the changes from baseline showed that PRU provides a consistent benefit among patients. PRU treatment also resulted in large ES of patient satisfaction, with regularity of bowel movement frequency as the most responsive item. PLSPM showed that improvement in patient satisfaction can largely be attributed to relief of abdominal and stool related symptoms ($r=0.6$).

Conclusion Prucalopride is highly effective in relief of abdominal and stool related symptoms. Relief of these symptoms is associated with a substantial improvement in patient satisfaction with bowel habit and treatment.

Competing interests R. Kerstens Employee of: Movetis NV, L. Vandeplassche Employee of: Movetis NV, D. Dubois Consultant for: Movetis NV, L. Wouters Consultant for: Movetis NV.

Keywords Constipation, Prucalopride.