Effect of tegaserod on work and daily activity: results from ZENSAA

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BACKGROUND

- Irritable bowel syndrome (IBS) is a chronic and episodic gastrointestinal motility and sensory disorder, characterized by abdominal pain/discomfort, bloating and altered bowel habit (constipation, diarrhea or alternating periods of both)
- IBS is known to have a significantly negative impact on patients' quality of life (QoL) by restricting their daily routines, social lives, personal relationships, and emotional well-being[1,2]
- IBS symptoms can have a detrimental effect on sufferers' work productivity and their professional development.[3] IBS-related absenteeism (missed days of work) and presenteeism (reduced on-the-job effectiveness) also impose a considerable financial burden on employers; US data highlight that direct and indirect costs are 50% higher for an employee with IBS than for an employee without IBS[4]
- Tegaserod has proven efficacy for the treatment of the multiple dysmotility and sensory symptoms of IBS with constipation (IBS-C), and a favorable safety profile[5–7]
- Tegaserod has also been shown to improve patients' QoL compared with placebo.[8,9] However, its effects on work-related productivity are unknown

OBJECTIVES

- The aim of this study was to evaluate the effect of tegaserod on work productivity and daily activity impairment of patients with IBS-C

METHODS

- Women (18–65 years) meeting Rome II criteria for IBS-C were randomized in a double-blind, placebo-controlled, multicenter study of tegaserod 6 mg b.i.d. or placebo (ZENSAA: Zelnorm in Europe, North and South America and Africa). The study comprised a 2-week treatment-free baseline period and two 4-week double-blind treatment periods (P1, P2), separated by a treatment-free interval
- Absenteeism, presenteeism, overall work productivity loss (absenteeism plus presenteeism) and daily activity impairment due to IBS symptoms during the previous 7 days were measured with the validated Work Productivity and Activity Impairment questionnaire for IBS,[9] modified to exclude diarrhea as an IBS symptom (WPAI:IBS-C)
- Patients completed WPAI:IBS-C at Baseline and at Weeks 2 and 4 of P1
- Analysis of covariance (ANCOVA) was performed for the change from Baseline to Week 2 and Week 4 for each WPAI:IBS-C measure. The covariates included in the ANCOVA were pooled center, treatment, age and baseline score

RESULTS

Patient characteristics

- A total of 2,660 women were randomized in P1, and of these, 1,675 (tegaserod [n=1,363], placebo [n=312]) were employed and completed WPAI:IBS-C
- Patients in the tegaserod and placebo groups were comparable for age and race. The mean age of patients was approximately 40.8 years and the majority of patients were Caucasian (approximately 86%) (Table 1)

RESULTS (cont'd)

Table 1. Baseline demographics of employed patients completing WPAI:IBS-C.

Characteristic	Tegaserod 6 mg b.i.d. (n=1,363)	Placebo (n=312)
Age (years), mean (SD)	40.8 (10.7)	40.7 (10.6)
Race, n (%)		
Caucasian	1,162 (85.3)	269 (86.2)
Black	45 (3.3)	10 (3.2)
Asian	12 (0.9)	3 (1.0)
Other	144 (10.6)	30 (9.6)

SD = standard deviation

- Women were recruited from 267 centers and grouped according to geographical region:
  - US (n=670)
  - Europe (n=721, recruited in Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, UK, Hungary, Italy, The Netherlands, Norway, Sweden)
  - South America (n=171, recruited in Argentina, Chile, Colombia, Ecuador, Peru)
  - other (n=95, recruited in Canada, Egypt, New Zealand, South Africa)
- Results for the 'other' category were not included in this analysis due to the small sample size and large geographical variation

Work productivity and activity impairment outcomes

- US patients in the tegaserod 6 mg b.i.d. group reported a decrease in absenteeism, presenteeism, work productivity loss and daily activity impairment at both Week 2 and Week 4. All improvements were significantly greater than those reported by patients given placebo (p=0.05 to 0.003) (Figure 1)
- European patients in the tegaserod group reported decreases in all work impairment measures and daily activity impairment at Week 2 and Week 4. Relative to placebo, tegaserod-treated patients experienced significantly greater improvements in daily activity at Week 2 (p=0.04), and significantly greater improvements in all measures at Week 4 (p=0.003 to 0.04) (Figure 2)
- South American patients receiving tegaserod reported improvements in all work and daily activity impairment measures at Week 2 and Week 4. Tegaserod-treated patients experienced a significant improvement in absenteeism at Week 2 (p=0.004), compared with patients in the placebo group (Figure 3). The small sample size (n=171) and the 4:1 ratio of tegaserod to placebo patients limited the analysis of the South American results

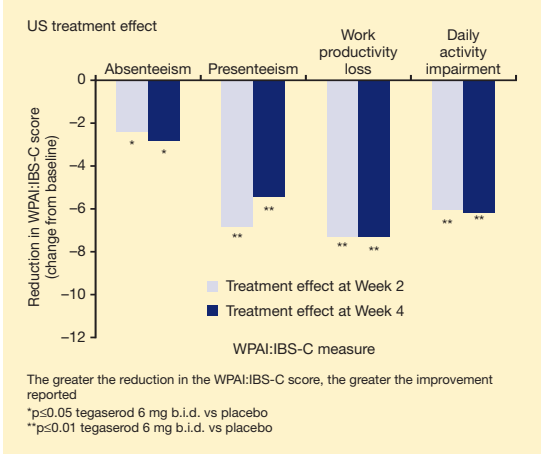

Figure 1. The effect of tegaserod treatment on WPAI:IBS-C score in US patients.

RESULTS (cont'd)

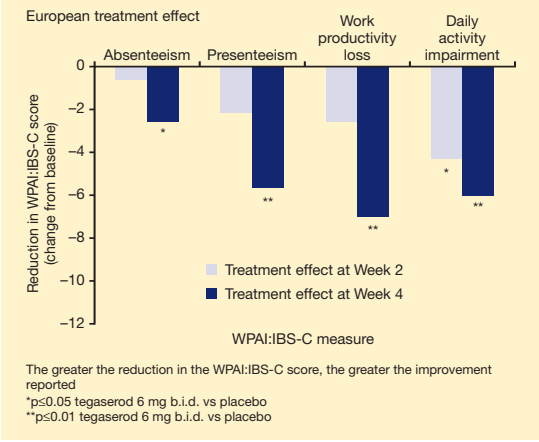

Figure 2. The effect of tegaserod treatment on WPAI:IBS-C score in European patients.

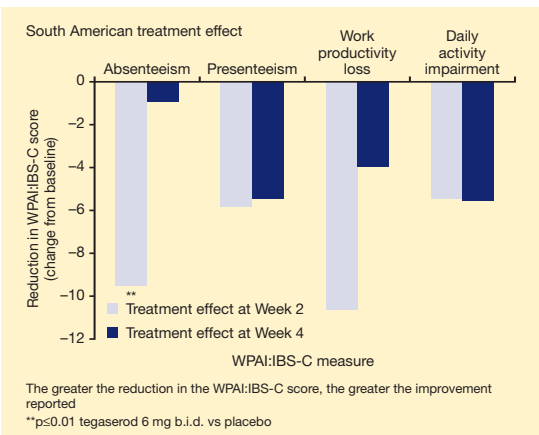

Figure 3. The effect of tegaserod treatment on WPAI:IBS-C score in South American patients.

CONCLUSIONS

- Compared with placebo, tegaserod 6 mg b.i.d. is associated with improvements in work productivity (decreased absenteeism and presenteeism) and daily activities in IBS-C patients from the US, Europe and South America
- This beneficial effect of tegaserod was seen at Week 2 of treatment and was maintained at Week 4

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