Tegaserod Helps IBS Patients' Work Attendance

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HONOLULU — The use of tegaserod in women with constipation-predominant irritable bowel syndrome resulted in improved work attendance and productivity in a large, open-label, naturalistic study designed to reflect actual clinical practice, Dr. Nigel Flook reported at the annual meeting of the American College of Gastroenterology.

The findings, from the observational Zelnorm Advancing Quality of life (ZAQ) study, have important implications for both quality of life and health economics. An earlier study showed that persons with IBS miss three times as many work days as colleagues without IBS, wrote Dr. Flook of the University of Alberta, Edmonton.

He reported on 2,381 women with abdominal pain and discomfort, bloating, and constipation who participated in the Novartis-sponsored ZAQ study. Three-fourths

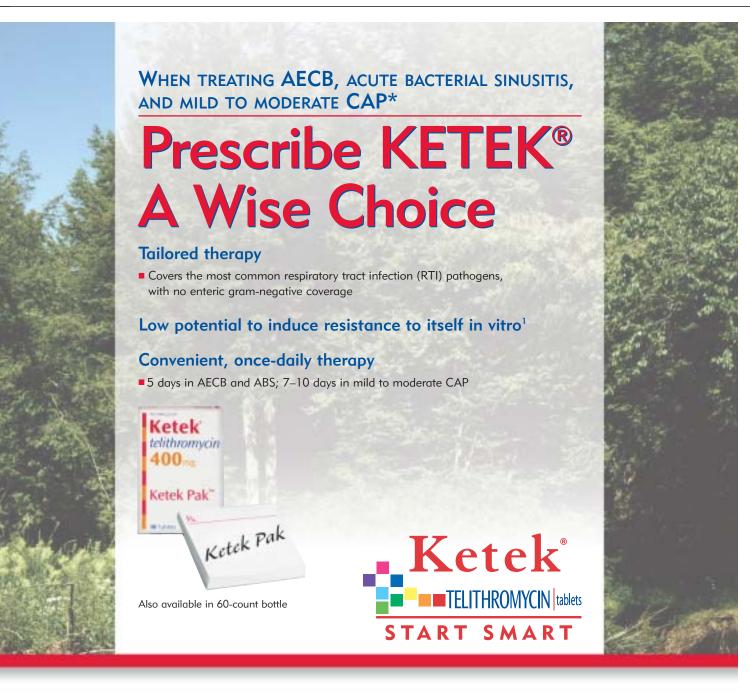
were at least 40 years old; one-fourth were older than 60. Overall, 78% reported at least a 2-year history of IBS symptoms, and 30% said they'd had IBS for more than 10 years.

A caveat for the ZAQ data concerns the possibility of selection bias. Only 20% of participants finished by returning the week-12 questionnaires, Dr. Flook said; data were collected at baseline and 12 weeks.

Baseline use of prescription and over-thecounter medications to treat GI symptoms was extremely common: 28% of participants were taking more than one prescription drug, and 40% were on more than one OTC drug for their IBS symptoms.

All participants were placed on 6 mg b.i.d. of tegaserod, an SSRI agonist that acts as a promotility agent and is the first drug approved for IBS.

Self-reported questionnaire data after 12 weeks' tegaserod treatment showed that 27% of patients missed fewer days at work or school, though 7% missed more days, compared with baseline.



gravis. KETEK® has the potential to prolong the QTc interval, which may lead to an increased risk for ventricular arrhythmias, including torsades de pointes. Thus, KETEK® should be avoided in patients with congenital prolongation of the QTc interval, and in patients with ongoing proarrhythmic conditions such as uncorrected hypokalemia or hypomagnesemia, clinically significant bradycardia, and in patients receiving Class IA (eg, quinidine and procainamide) or Class III (eg, dofetilide) antiarrhythmic agents. KETEK® may cause visual disturbances particularly in slowing the ability to accommodate and the ability to release accommodation. Visual disturbances included blurred vision, difficulty focusing, and diplopia. There have been post marketing adverse event reports of syncope. Patients should be cautioned about the potential effects of visual disturbance and syncope on driving or engaging in potentially hazardous activities. Hepatic dysfunction, including increased liver enzymes and hepatitis, with or without jaundice, has been reported

with the use of KETEK®. Caution should be used in patients with a previous history of hepatitis/jaundice associated with the use of KETEK®. Use of simvastatin, lovastatin, or atorvastatin concomitantly with KETEK® should be avoided. If KETEK® is prescribed, therapy with simvastatin, lovastatin, or atorvastatin should be suspended during the course of treatment. Concomitant treatment of KETEK® with rifampin, a CYP 3A4 inducer, should be avoided. Most adverse events were mild to moderate and included diarrhea (KETEK®, 10.8%; comparators, 8.6%), nausea (7.9%; 4.6%), headache (5.5%; 5.8%), dizziness (3.7%; 2.7%), vomiting (2.9%; 2.2%), loose stools (2.3%; 1.5%). <1% discontinuation rate due to diarrhea in controlled clinical trials (0.9% for KETEK® vs 0.7% for comparators).

Please see brief summary of prescribing information on adjacent pages.

Reference: 1. Clarebout G, Leclercq R. Fluorescence assay for studying the ability of macrolides to induce production of ribosomal methylase. *Antimicrob Agents Chemother*. 2002;46:2269-2272