Claudication Drug May Cut Cerebrovascular Events

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BALTIMORE — Treatment with the claudication drug cilostazol was linked to a significant drop in the rate of cerebrovascular events in a post hoc analysis of data collected from more than 1,400 patients with peripheral artery disease.

Further studies on cilostazol for preventing strokes are needed, Dr. William M. Stone said at the Vascular Annual Meeting. He and his associates looked at data collected in a postmarketing, safety study of cilostazol that compared the long-term effect of treatment with placebo in a randomized study of patients with intermittent claudication secondary to peripheral arterial disease.

The study was sponsored by Otsuka, which markets cilostazol (Pletal). The drug was approved by the Food and Drug Administration in 1999 to treat claudication. Dr. Stone disclosed no financial relationships with Otsuka, but said that one of his associates who also worked on the analysis was a consultant to and received honoraria from Otsuka.

The Cilostazol: A Study on Long-Term Effects (CASTLE) study enrolled patients in 2001-2004. The results have not yet been published.

A total of 717 patients were randomized to a standard regimen with cilostazol and 718 to placebo. The average duration of treatment was 515 days. The average age of the patients was 66 years. The pattern of concomitant medication use and the prevalence of cerebrovascular risk factors were similar in both arms.

Forty-four placebo patients (6%) had cerebrovascular events, and 23 patients treated with cilostazol (3%) had cerebrovascular events. The difference in rate between the two groups was statistically significant, said Dr. Stone, who is a vascular surgeon at the Mayo Clinic in Scottsdale, Ariz. ■

QUIT RATES SUPERIOR TO ZYBAN® AT 12 WEEKS IN 2 HEAD-TO-HEAD CLINICAL TRIALS (*P*=.0001)[1,2]*

44% of subjects who received CHANTIX 1 mg bid quit smoking by the end of 12 weeks vs:

- Approximately 30% of subjects who received Zyban 150 mg bid
- Approximately 17.5% of subjects who received placebo

WELL-STUDIED TOLERABILITY AND SAFETY PROFILE

- The most common adverse reactions included nausea, sleep disturbance, constipation, flatulence, and vomiting. Nausea occurred in 30% of subjects while 3% discontinued due to nausea

CONVENIENT *PAK* DOSING

- *PAK*s are designed to simplify prescribing and to help improve patient adherence

GET QUIT™ **SUPPORT PLAN**

- A personalized behavioral support program designed to address critical behavioral components of smoking cessation, such as relapse

Patients should be encouraged to continue to attempt to quit if they have early lapses after quit day.

Dosage adjustment with CHANTIX is recommended in patients with severe renal impairment or in patients undergoing hemodialysis.

Smoking cessation, with or without treatment with CHANTIX, may alter the pharmacokinetics or pharmacodynamics of some drugs, such as theophylline, warfarin, and insulin. Dosage adjustment for these drugs may be necessary.

CHANTIX™ (varenicline) TABLETS

TURN MORE SMOKERS INTO QUITTERS

*Results from 2 identically designed, 52-week (12 weeks pharmacotherapy, 40 weeks nonpharmacotherapy follow-up), randomized, double-blind, parallel-group, multicenter clinical trials (study 4: N=1022; study 5: N=1023) in which CHANTIX 1 mg bid was compared with Zyban 150 mg bid and placebo for efficacy and safety in smoking cessation. For trial inclusion, subjects must have smoked at least 10 cigarettes per day over the past year, with no period of abstinence greater than 3 months, and must have been bupropion naive. The primary efficacy end point in both trials was the carbon monoxide (CO)–confirmed 4-week continuous abstinence rate for weeks 9 through 12, defined as the percentage of subjects who reported no smoking (not even a puff) or use of any nicotine-containing products confirmed by an exhaled CO measurement of 10 ppm or less at each clinic visit. (Studies 4 and 5 from the CHANTIX package insert.)[1,3-5]

Subjects were provided with an educational booklet on smoking cessation and received up to 10 minutes of smoking cessation counseling at each clinic visit in accordance with Agency for Healthcare Research and Quality guidelines.[5]