

Bazedoxifene May Not Harm the Endometrium

BY FRAN LOWRY
Orlando Bureau

Bazedoxifene, a novel selective estrogen-receptor modulator, is as safe as placebo in terms of effects on the endometrium and promises to be an excellent new therapy for the prevention and treatment of postmenopausal osteoporosis, Dr. David F. Archer said at the annual meeting of the North American Menopause Society. Dr. Archer, professor of obstetrics and gy-

necology at Eastern Virginia Medical School, Norfolk, and a consultant for Wyeth Pharmaceuticals, the sponsor of the study, presented data on endometrial safety in a subset of women who were participants in a large phase III trial comparing the efficacy of bazedoxifene, raloxifene, and placebo in reducing the relative risk of new vertebral fractures in 7,492 subjects.

The results of that trial, presented at the annual meeting of the American Society for Bone and Mineral Research, found

bazedoxifene at 20 mg or 40 mg per day significantly reduced new vertebral fractures, compared with placebo. Similar results also were obtained with raloxifene 60 mg per day. However, in the subanalysis raloxifene was linked to more endometrial hyperplasia, Dr. Archer said.

The endometrial safety substudy focused on 643 women who had transvaginal ultrasonography at baseline and at month 24. Endometrial biopsies also were performed at these two time points.

Endometrial thickness between baseline and 24 months increased by 0.1 mm with both doses of bazedoxifene and placebo, compared with an increase of 0.3 mm with raloxifene, Dr. Archer said.

About five women in each of the four treatment arms had 4 mm or more growth in endometrial thickness, but when they were biopsied, no evidence of hyperplasia was detected.

Food and Drug Administration approval of bazedoxifene is pending. ■

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

- PAKs 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.³