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 gynecology 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. ■