

## SERM Education Project Reference List

- Abraham L, Pinkerton JV, Messig M, Ryan KA, Komm BS, Mirkin S. Menopause-specific quality of life across varying menopausal populations with conjugated estrogens/bazedoxifene. *Maturitas*. 2014;78(3):212-218.
- Archer DF, Carr BR, Pinkerton JV, Taylor HS, Constantine GD. Effects of ospemifene on the female reproductive and urinary tracts: translation from preclinical models into clinical evidence. *Menopause*. 2015;22(7):786-796.
- Archer DF, Lewis V, Carr BR, Olivier S, Pickar JH. Bazedoxifene/conjugated estrogens (BZA/CE): incidence of uterine bleeding in postmenopausal women. *Fertil Steril*. 2009;92(3):1039-1044.
- Archer DF. The gynecologic effects of lasofoxifene, an estrogen agonist/antagonist, in postmenopausal women. *Menopause*. 2011;18(1):6-7.
- Bachmann G, Bobula J, Mirkin S. Effects of bazedoxifene/conjugated estrogens on quality of life in postmenopausal women with symptoms of vulvar/vaginal atrophy. *Climacteric*. 2010;13(2):132-140.
- Bachmann G, Gass M, Kagan R, Moffett A, Barcomb L, Symons J. Lasofoxifene (LASO), a next generation selective estrogen response modulator (SERM) improves dyspareunia in postmenopausal women with vaginal atrophy (VA) [abstract]. *Menopause*. 2005;12(2):238.
- Bachmann G, Gass M, Moffett A, Portman D, Symons J. Lasofoxifene improves symptoms associated with vaginal atrophy [abstract]. *Menopause*. 2004;11(6):669. Abstract P-63.
- Bachmann GA, Komi JO; Ospemifene Study Group. Ospemifene effectively treats vulvovaginal atrophy in postmenopausal women: results from a pivotal phase 3 study. *Menopause*. 2010;17(3):480-486.
- Barrett-Connor E, Grady D, Sashegyi A, et al; MORE Investigators (Multiple Outcomes of Raloxifene Evaluation). Raloxifene and cardiovascular events in osteoporotic postmenopausal women: four-year results from the MORE (Multiple Outcomes of Raloxifene Evaluation) randomized trial. *JAMA*. 2002;287(7):847-857.
- Barrett-Connor E, Mosca L, Collins P, et al; Raloxifene Use for The Heart (RUTH) Trial Investigators. Effects of raloxifene on cardiovascular events and breast cancer in postmenopausal women. *N Engl J Med*. 2006;355(2):125-137.
- Berga SL. Profile of ospemifene in the breast. *Reprod Sci*. 2013;20(10):1130-1136.
- Bülbül NH, Ozden S, Dayicioglu V. Effects of hormone replacement therapy on mammographic findings. *Arch Gynecol Obstet*. 2003;268(1):5-8.
- Burich R, Mehta N, Wurz G, et al. Ospemifene and 4-hydroxyospemifene effectively prevent and treat breast cancer in the MTag.Tg transgenic mouse model. *Menopause*. 2012;19(1):96-103.
- Carneiro AL, de Cassia de Maio Dardes R, Haidar MA. Estrogens plus raloxifene on endometrial safety and menopausal symptoms—semisystematic review. *Menopause*. 2012;19(7):830-834.
- Conjugated estrogens/bazedoxifene (Duavee) for menopausal symptoms and prevention of osteoporosis. *Med Lett Drugs Ther*. 2014;56(1441):33-34.
- Constantine G, Graham S, Koltun WD, Kingsberg SA. Assessment of ospemifene or lubricants on clinical signs of VVA. *J Sex Med*. 2014;11(4):1033-1041.

Constantine G, Graham S, Portman DJ, Rosen RC, Kingsberg SA. Female sexual function improved with ospemifene in postmenopausal women with vulvar and vaginal atrophy: results of a randomized, placebo-controlled trial. *Climacteric*. 2015;18(2):226-232.

Constantine GD, Goldstein SR, Archer DF. Endometrial safety of ospemifene: results of the phase 2/3 clinical development program. *Menopause*. 2015;22(1):36-43.

Crandall CJ, Aragaki AK, Cauley JA, et al. Breast tenderness after initiation of conjugated equine estrogens and mammographic density change. *Breast Cancer Res Treat*. 2012;131(3):969-979.

Crandall CJ, Aragaki AK, Cauley JA, et al. Breast tenderness and breast cancer risk in the estrogen plus progestin and estrogen-alone women's health initiative clinical trials. *Breast Cancer Res Treat*. 2012;132(1):275-285.

Crandall CJ, Karlamangla A, Huang MH, Ursin G, Guan M, Greendale GA. Association of new-onset breast discomfort with an increase in mammographic density during hormone therapy. *Arch Intern Med*. 2006;166(15):1578-1584.

Crew K. Addressing barriers to uptake of breast cancer chemoprevention for patients and providers. *Am Soc Clin Oncol Educ Book*. 2015;35:e50-e58.

Cummings SR, Eckert S, Krueger KA, et al. The effect of raloxifene on risk of breast cancer in postmenopausal women: results from the MORE randomized trial. Multiple Outcomes of Raloxifene Evaluation. *JAMA*. 1999;281(23):2189-2197.

Cummings SR, Ensrud K, Delmas PD, LaCroix AZ, et al; PEARL Study Investigators. Lasofoxifene in postmenopausal women with osteoporosis. *N Engl J Med*. 2010;362(8):686-696.

Davidson NE, Kensler TW. "MAPping" the course of chemoprevention in breast cancer. *N Engl J Med*. 2011;364(25):2463-2464.

Day R, Ganz PA, Costantino JP, Cronin WM, Wickerham DL, Fisher B. Health-related quality of life and tamoxifen in breast cancer prevention: a report from the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *J Clin Oncol*. 1999;17(9):2659-2669.

Day R; National Surgical Adjuvant Breast and Bowel Project P-1 study (NSABP-1). Quality of life and tamoxifen in a breast cancer prevention trial: a summary of findings from the NSABP P-1 study. National Surgical Adjuvant Breast and Bowel Project. *Ann N Y Acad Sci*. 2001;949:143-150.

de Villiers TJ, Chines AA, Palacios S, et al. Safety and tolerability of bazedoxifene in postmenopausal women with osteoporosis: results of a 5-year, randomized, placebo-controlled phase 3 trial. *Osteoporos Int*. 2011;22(2):567-576.

de Villiers TJ, Gass ML, Haines CJ, et al. Global consensus statement on menopausal hormone therapy. *Climacteric*. 2013;16(2):203-204.

Delmas PD, Ensrud KE, Adachi JD, et al; Multiple Outcomes of Raloxifene Evaluation Investigators. Efficacy of raloxifene on vertebral fracture risk reduction in postmenopausal women with osteoporosis: four-year results from a randomized clinical trial. *J Clin Endocrinol Metab*. 2002;87(3):3609-3617.

Eastell R, Adachi J, Hamer K, et al. The effects of raloxifene on incident vertebral fractures in postmenopausal women with osteoporosis: 4-year results from the MORE trial [abstract]. *J Bone Miner Res*. 2000;15(suppl 1):S229. Abstract F418.

Ensrud K, LaCroix A, Thompson JR, et al. Lasofoxifene and cardiovascular events in postmenopausal women with osteoporosis: Five-year results from the Postmenopausal Evaluation and Risk Reduction with Lasofoxifene (PEARL) trial. *Circulation*. 2010;122(17):1716-1724.

Ettinger B, Black DM, Mitlak BH, et al. Reduction of vertebral fracture risk in postmenopausal women with osteoporosis treated with raloxifene: results from a 3-year randomized clinical trial. Multiple Outcomes of Raloxifene Evaluation (MORE) Investigators. *JAMA*. 1999;282(7):637-645. Erratum in *JAMA*. 1999;282(22):2124.

Ettinger B, Pressman A. Continuation of postmenopausal hormone replacement therapy in a large health maintenance organization: transdermal matrix patch versus oral estrogen therapy. *Am J Manag Care*. 1999;5(6):779-785.

Fagerlin A, Dillard AJ, Smith DM, et al. Women's interest in taking tamoxifen and raloxifene for breast cancer prevention: response to a tailored decision aid. *Breast Cancer Res Treat*. 2011;127(3):681-688.

Fagerlin A, Zikmund-Fisher BJ, et al. Women's decisions regarding tamoxifen for breast cancer prevention: responses to a tailored decision aid. *Breast Cancer Res Treat*. 2010;119(3):613-620.

Fisher B, Costantino JAP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *J Natl Cancer Inst*. 1998;90(18):1371-1388.

Fisher B, Costantino JP, Wickerham DL, et al. Tamoxifen for the prevention of breast cancer: current status of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst*. 2005;97(22):1652-1662.

Gass M, Portman D, Bachmann G, Moffett A, Symons J. Clinical signs of vaginal atrophy are improved by the SERM lasofoxifene [abstract]. *Menopause*. 2004;11(6):670. Abstract P-68.

Goldstein SR, Bachmann GA, Koninckx PR, Lin VH, Portman DJ, Ylikorkala O; Ospemifene Study Group. Ospemifene 12-month safety and efficacy in postmenopausal women with vulvar and vaginal atrophy. *Climacteric*. 2014;17(2):173-182.

Goldstein SR, Kagan R. Incidence of bleeding or spotting with a conjugated estrogen/bazedoxifene compound compared to conjugated estrogen/progestogen to placebo [abstract]. *Menopause*. 2015;22(12):1384. Abstract P-31.

Goldstein SR, Neven P, Cummings S, et al. Postmenopausal Evaluation and Risk Reduction With Lasofoxifene (PEARL) trial: 5-year gynecological outcomes. *Menopause*. 2011;18(1):17-22.

Harvey JA, Pinkerton JV, Barakat EC, Shi H, Chines AA, Mirkin S. Breast density changes in a randomized controlled trial evaluating bazedoxifene/conjugated estrogens. *Menopause*. 2013;20(2):138-145.

Harvey JA, Pinkerton JV, Barakat EC, Shi H, Mirkin S, Chines AA. Evaluation of changes in mammographic breast density associated with bazedoxifene/conjugated estrogens in postmenopausal women [abstract]. *Endocr Rev*. 2011;32(3). Abstract P1-79.

Holli K, Valavaara R, Blanco G, et al. Safety and efficacy results of a randomized trial comparing adjuvant toremifene and tamoxifen in postmenopausal patients with node-positive breast cancer. Finnish Breast Cancer Group. *J Clin Oncol*. 2000;18(20):3487-3494.

Kagan R, Williams RS, Pan K, Mirkin S, Pickar JH. A randomized, placebo- and active-controlled trial of bazedoxifene/conjugated estrogens for treatment of moderate to severe vulvar/vaginal atrophy in postmenopausal women. *Menopause*. 2010;17(2):281-289.

Kawate H, Takayanagi R. Efficacy and safety of bazedoxifene for postmenopausal osteoporosis. *Clin Interv Aging*. 2011;6:151-160.

Kessel B, Nachtigall L, Plouffe L, Siddhanti S, Rosen A, Parsons A. Effect of raloxifene on sexual function in postmenopausal women. *Climacteric*. 2003;6(3):248-256.

Kessel B, Nachtigall L, Plouffe L, Siddhanti S, Rosen A, Parsons A. Effect of raloxifene on sexual function in postmenopausal women. *Climacteric*. 2003;6(3):248-256.

Komm BS, Thompson JR, Mirkin S. Cardiovascular safety of conjugated estrogens plus bazedoxifene: meta-analysis of the SMART trials. *Climacteric*. 2015;18(4):503-511.

LaCroix AZ, Powles T, Osborne CK, et al; PEARL Investigators. Breast cancer incidence in the randomized PEARL trial of lasofoxifene in postmenopausal osteoporotic women. *J Natl Cancer Inst*. 2010;102(22):1706-1715.

Langer RD, Manson JE, Allison MA. Have we come full circle—or moved forward? The Women’s Health Initiative 10 years on. *Climacteric*. 2012;15(3):206-212.

Lindsay R, Gallagher JC, Kagan R, Pickar JH, Constantine G. Efficacy of tissue-selective estrogen complex (TSEC) of bazedoxifene/conjugated estrogens (BZA/CE) for osteoporosis prevention in at-risk postmenopausal women. *Fertil Steril*. 2009;92(3):1045-1052.

Lobo RA, Pinkerton JV, Gass ML, et al. Evaluation of bazedoxifene/conjugated estrogens for the treatment of menopausal symptoms and effects on metabolic parameters and overall safety profile. *Fertil Steril*. 2009;92(3):1025-1038.

Loehberg CR, Jud SM, Haeberle L, et al. Breast cancer risk assessment in a mammography screening program and participation in the IBIS-II chemoprevention trial. *Breast Cancer Res Treat*. 2010;121(1):101-110.

Love RR, Kurtycz DF, Dumesic DA, Laube DW, Yang Y. The effects of tamoxifen on the vaginal epithelium in postmenopausal women. *J Womens Health Gend Based Med*. 2000;9(5):559-563.

Management of osteoporosis in postmenopausal women: 2010 position statement of The North American Menopause Society. *Menopause*. 2010;17(1):25-54; quiz 55-56.

Martino S, Cauley JA, Barrett-Connor E, et al; CORE Investigators. Continuing outcomes relevant to Evista: breast cancer incidence in postmenopausal osteoporotic women in a randomized trial of raloxifene. *J Natl Cancer Inst*. 2004;96(23):1751-1761.

McClung MR, Siris E, Cummings S, et al. Prevention of bone loss in postmenopausal women treated with lasofoxifene compared with raloxifene. *Menopause*. 2006;13(3):377-386.

McNicholas MM, Heneghan JP, Milner MH, Tunney T, Hourihane JB, MacErlaine DP. Pain and increased mammographic density in women receiving hormone replacement therapy: a prospective study. *AJR Am J Roentgenol*. 1994;163(2):311-315.

Mirkin S, Archer DF, Taylor HS, Pickar JH, Komm BS. Differential effects of menopausal therapies on the endometrium. *Menopause*. 2014;21(8):899-908.

Mirkin S, Komm BS, Pan K, Chines AA. Effects of bazedoxifene/conjugated estrogens on endometrial safety and bone in postmenopausal women. *Climacteric*. 2013;16(3):338-346.

Mirkin S, Pickar JH. Management of osteoporosis and menopausal symptoms: focus on bazedoxifene/conjugated estrogen combination. *Int J Womens Health*. 2013;5:465-475.

Mortimer JE, Boucher L, Baty J, Knapp DL, Ryan E, Rowland JH. Effect of tamoxifen on sexual functioning in patients with breast cancer. *J Clin Oncol*. 1999;17(5):1488-1492.

Mosca L, Barrett-Connor E, Wenger NK, et al. Design and methods of the Raloxifene Use for The Heart (RUTH) study. *Am J Cardiol*. 2001;88(4):392-395.

Mosca L, Grady D, Barrett-Connor E, et al. Effect of raloxifene on stroke and venous thromboembolism according to subgroups in postmenopausal women at increased risk of coronary heart disease. *Stroke*. 2009;40(1):147-155.

O'Connell MB. Prescription drug therapies for prevention and treatment of postmenopausal osteoporosis. *J Manag Care Pharm*. 2006;12(6 suppl A):S10-S19; quiz S26-28.

Owens WL, Gallagher TJ, Kincheloe MJ, Ruetten VL. Implementation in a large health system of a program to identify women at high risk for breast cancer. *J Oncol Pract*. 2011;7(2):85-88.

Parsons A, Merritt D, Rosen A, Heath H 3rd, Siddhanti S, Plouffe L Jr; Study Groups on the Effects of Raloxifene HCl With Low-Dose Premarin Vaginal Cream. Effect of raloxifene on the response to conjugated estrogen vaginal cream or nonhormonal moisturizers in postmenopausal vaginal atrophy. *Obstet Gynecol*. 2003;101(2):346-352.

Pickar JH, Yeh IT, Bachmann G, Speroff L. Endometrial effects of a tissue selective estrogen complex (TSEC) containing bazedoxifene/conjugated estrogens as a menopausal therapy. *Fertil Steril*. 2009;92(3):1018-1024.

Pinkerton JV, Abraham L, Bushmakin AG, et al. Evaluation of the efficacy and safety of bazedoxifene/conjugated estrogens for secondary outcomes including vasomotor symptoms in postmenopausal women by years since menopause in the Selective estrogens, Menopause and Response to Therapy (SMART) trials. *J Womens Health (Larchmt)*. 2014;23(1):18-28.

Pinkerton JV, Archer DF, Utian WH, et al. Bazedoxifene effects on the reproductive tract in postmenopausal women at risk for osteoporosis. *Menopause*. 2009;16(6):1102-1108.

Pinkerton JV, Harvey JA, Lindsay R, Pan K, Chines AA, Mirkin S, et al; SMART-5 Investigators. Effects of bazedoxifene/conjugated estrogens on the endometrium and bone: a randomized trial. *J Clin Endocrinol Metab*. 2014;99(2):E189-E198.

Pinkerton JV, Harvey JA, Pan K, et al. Breast effects of bazedoxifene-conjugated estrogens: a randomized controlled trial. *Obstet Gynecol*. 2013;121(5):959-968.

Pinkerton JV, Komm BS, Mirkin S. Tissue selective estrogen complex combinations with bazedoxifene/conjugated estrogens as a model. *Climacteric*. 2013;16(6):618-628.

Pinkerton JV, Pan K, Abraham L, et al. Sleep parameters and health-related quality of life with bazedoxifene/conjugated estrogens: a randomized trial. *Menopause*. 2014;21(3):252-259.

Pinkerton JV, Shifren JL, La Valleur J, Rosen A, Roesinger M, Siddhanti S. Influence of raloxifene on the efficacy of an estradiol-releasing ring for treating vaginal atrophy in postmenopausal women. *Menopause*. 2003;10(1):45-52.

Pinkerton JV, Stanczyk FZ. Clinical effects of selective estrogen receptor modulators on vulvar and vaginal atrophy. *Menopause*. 2014;21(3):309-319.

Pinkerton JV, Utian WH, Constantine GD, Olivier S, Pickar JH. Relief of vasomotor symptoms with the tissue-selective estrogen complex containing bazedoxifene/conjugated estrogens: a randomized, controlled trial. *Menopause*. 2009;16(6):1116-1124. Erratum in: *Menopause*. 2015;22(2):245.

Plouffe L Jr. Selective estrogen receptor modulators (SERMs) in clinical practice. *J Soc Gynecol Investig.* 2000;7(1 suppl):S38-S46.

Portman D, Palacios S, Nappi RE, Mueck AO. Ospemifene, a non-oestrogen selective oestrogen receptor modulator for the treatment of vaginal dryness associated with postmenopausal vulvar and vaginal atrophy: a randomised, placebo-controlled, phase III trial. *Maturitas.* 2014;78(2):91-98.

Portman DJ, Bachmann GA, Simon JA; Ospemifene Study Group. Ospemifene, a novel selective estrogen receptor modulator for treating dyspareunia associated with postmenopausal vulvar and vaginal atrophy. *Menopause.* 2013;20(6):623-630.

Portman DJ, Moffett AH, Bachman GA, West C, Symons J. Lasofoxifene, a selective estrogen receptor modulator, improves objective measures of vaginal atrophy. *Obstet Gynecol.* 2004;103:25S-26S.

Qu Q, Zheng H, Dahllund J, et al. Selective estrogenic effects of a novel triphenylethylene compound, FC1271a, on bone, cholesterol level, and reproductive tissues in intact and ovariectomized rats. *Endocrinology.* 2000;141(2):809-820.

Silverman SL, Chines AA, Kendler DL, et al; Bazedoxifene Study Group. Sustained efficacy and safety of bazedoxifene in preventing fractures in postmenopausal women with osteoporosis: results of a 5-year, randomized, placebo-controlled study. *Osteoporos Int.* 2012;23(1):351-363.

Silverman SL, Christiansen C, Genant HK, et al. Efficacy of bazedoxifene in reducing new vertebral fracture risk in postmenopausal women with osteoporosis: results from a 3-year, randomized, placebo-, and active-controlled clinical trial. *J Bone Miner Res.* 2008;23(12):1923-1934.

Simon J, Portman D, Mabey RG Jr; Ospemifene Study Group. Long-term safety of ospemifene (52-week extension) in the treatment of vulvar and vaginal atrophy in hysterectomized postmenopausal women. *Maturitas.* 2014;77(3):274-281.

Simon JA, Lin VH, Radovich C, Bachmann GA; Ospemifene Study Group. One-year long-term safety extension study of ospemifene for the treatment of vulvar and vaginal atrophy in postmenopausal women with a uterus. *Menopause.* 2013;20(4):418-427.

Siris E, Adachi JD, Lu Y, et al. Effects of raloxifene on fracture severity in postmenopausal women with osteoporosis: results from the MORE study. Multiple Outcomes of Raloxifene Evaluation. *Osteoporos Int.* 2002;13(11):907-913.

Smith MR, Morton RA, Barnette KG, et al. Toremifene to reduce fracture risk in men receiving androgen deprivation therapy for prostate cancer. *J Urol.* 2010;184(4):1316-1321.

Steel SA, Albertazzi P, Howarth EM, Purdie DW. Factors affecting long-term adherence to hormone replacement therapy after screening for osteoporosis. *Climacteric.* 2003;6(2):96-103.

Stevenson JC, Chines A, Pan K, Ryan KA, Mirkin S. A pooled analysis of the effects of conjugated estrogens/bazedoxifene on lipid parameters in postmenopausal women from the Selective estrogens, Menopause, and Response to Therapy (SMART) trials. *J Clin Endocrinol Metab.* 2015;100(6):2329-2338.

Stovall DW, Utian WH, Gass ML, et al. The effects of combined raloxifene and oral estrogen on vasomotor symptoms and endometrial safety. *Menopause.* 2007;14(3 pt 1):510-517.

Stuenkel CA, Gass ML, Manson JE, et al. A decade after the Women's Health Initiative—the experts do agree. *Menopause.* 2012;19(8):846-847.

Taras TL, Wurz GT, DeGregorio MW. In vitro and in vivo biologic effects of ospemifene (FC-1271a) in breast cancer. *J Steroid Biochem Mol Biol.* 2001;77(4-5):271-279.

Taras TL, Wurz GT, DeGregorio MW. In vitro and in vivo biologic effects of ospemifene (FC-1271a) in breast cancer. *J Steroid Biochem Mol Biol*. 2001;77(4-5):271-279.

Utian W, Yu H, Bobula J, Mirkin S, Olivier S, Pickar JH. Bazedoxifene/conjugated estrogens and quality of life in postmenopausal women. *Maturitas*. 2009;63(4):329-335.

Visvanathan K, Hurley P, Bantug E, et al. Use of pharmacologic interventions for breast cancer risk reduction: American Society of Clinical Oncology clinical practice guideline. *J Clin Oncol*. 2013;31(23):2942-2962.

Vogel CL, Johnston MA, Capers C, Braccia D. Toremifene for breast cancer: a review of 20 years of data. *Clin Breast Cancer*. 2014;14(1):1-9.

Vogel VG, Costantino JP, Wickerham DL, et al; National Surgical Adjuvant Breast and Bowel Project (NSABP). Effects of tamoxifen vs raloxifene on the risk of developing invasive breast cancer and other disease outcomes: the NSABP Study of Tamoxifen and Raloxifene (STAR) P-2 trial. *JAMA*. 2006;295(23):2727-2741. Erratum in: *JAMA*. 2006;296(24):2926. *JAMA*. 2007;298(9):973.

Vogel VG, Costantino JP, Wickerham DL, et al; National Surgical Adjuvant Breast and Bowel Project. Update of the National Surgical Adjuvant Breast and Bowel Project Study of Tamoxifen and Raloxifene (STAR) P-2 Trial: Preventing breast cancer. *Cancer Prev Res (Phila)*. 2010;3(6):696-706.