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Pfizer Response To Ongoing Evaluation Of Hormone Therapy And Breast Cancer, And What It Means For Menopausal Women Who Have Had A Hysterectomy

NEW YORK, N.Y., March 15 - A new review published March 15th in the *Journal of the National Cancer Institute* (JNCI), entitled "Changing Concepts: Menopausal Hormone Therapy and Breast Cancer," concludes that estrogen-alone therapy poses no increased risk of breast cancer for postmenopausal women who have had a hysterectomy.

For women who have not had a hysterectomy, the review reiterates that the risk of breast cancer is increased when estrogen is combined with progestin. This is a known risk and is cited in all hormone therapy product labeling.

This new review adds to the evolving scientific discussion that estrogen-alone therapy is an important treatment option for women who have had a hysterectomy and are seeking relief from moderate-to-severe menopausal symptoms.

Ongoing analysis of findings from the Women's Health Initiative (WHI) is helping the scientific community reevaluate the benefits and risks of estrogen-alone therapy with Premarin. Several recent publications, including the review published in the JNCI, reexamine the benefit-risk profile of estrogen-alone therapy in menopausal women who have had a hysterectomy, especially those who initiate treatment 10 years or less after entering menopause. These include:

- "Conjugated equine oestrogen and breast cancer incidence and mortality in postmenopausal women with hysterectomy: extended follow-up of the Women's Health Initiative randomised placebo-controlled trial." Anderson et al. *The Lancet Oncology*, March 7, 2012.

- "Health Outcomes After Stopping Conjugated Equine Estrogens Among Postmenopausal Women with Prior Hysterectomy." LaCroix et al. *Journal of the American Medical Association*, April 5, 2011.

Expert scientific organizations, such as the Endocrine Society (ENDO), the International Menopause Society (IMS) and the North American Menopause Society (NAMS), recognize the effectiveness of hormone therapy for the appropriate menopausal patient. The U.S. Food and Drug Administration (FDA) also describes hormone therapy as "the most effective FDA-approved medicine for relief of hot flashes, night sweats or vaginal dryness" associated with menopause.

"At Pfizer, we have always believed that women deserve to have comprehensive conversations with healthcare providers about their menopause experience, including discussion of their symptoms and medical history," said Gail Cawkwell, MD, PhD, Vice President of Medical Affairs, Pfizer Inc. "These discussions have an impact on women's health and wellness at menopause and beyond. Menopausal women should have informed, balanced discussions of all treatment options available to them, including Premarin hormone therapy which has been studied in clinical trials in thousands of women." Approximately 46 million women in the U.S. are of menopausal age, and about nine million report suffering from moderate to severe symptoms.

Premarin (conjugated estrogen tablets, USP) is a conjugated equine estrogen and the number one prescribed branded estrogen therapy in the United States. Premarin is used to reduce moderate-to-severe hot flashes, to treat moderate-to-severe dryness, itching and burning in and around the vagina, and to help reduce the chances of getting osteoporosis.

The benefit-risk profile of Premarin is well established. There is an increased risk of blood clots and stroke seen in women who use estrogen therapy. Hormone therapy should not be used to prevent heart disease or dementia. Hormone therapy should be prescribed at the 'lowest effective dose and for the shortest duration consistent with treatment goals and risks for the individual woman,' and women should talk regularly with their doctors about whether treatment is still appropriate for them.

About the Women's Health Initiative

The WHI was a 15-year research program conducted by the National Institutes of Health. The hormone therapy trial was designed to investigate the long-term benefits and risks of estrogen plus progestin therapy (Prempro) and estrogen-alone therapy (Premarin) in the primary prevention of cardiovascular disease and other selected chronic diseases, including:

- Coronary heart disease (CHD), defined as a heart attack or CHD death
- Invasive breast cancer
- Stroke
- Venous thromboembolism
- Fracture
- Colorectal cancer

The WHI did not evaluate the primary indications of estrogen plus progestin and estrogen-alone, i.e., relief of moderate-to-severe-menopausal symptoms such as hot flashes, night sweats and vaginal dryness, as well as the prevention of postmenopausal osteoporosis, in the overall benefit-risk assessment. Also, WHI participants were, on average, 63 years of age at the start of the study, and most were asymptomatic.

Indications

PREMARIN (conjugated estrogens tablets, USP) and PREMPRO (conjugated estrogens/medroxyprogesterone acetate tablets) are prescribed after menopause to reduce moderate to severe hot flashes; to treat moderate to severe dryness, itching, and burning, in and around the vagina; and to help reduce chances of getting osteoporosis (thin weak bones).

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PREMARIN (an estrogen mixture) and PREMPRO (conjugated estrogens/medroxyprogesterone acetate tablets)?

- Do not use estrogens with progestins to prevent heart disease, heart attacks, strokes, or dementia (decline of brain function)
- Using estrogens with progestins may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots
- Using estrogens with progestins may increase your chance of getting dementia, based on a study of women age 65 years or older
- Do not use estrogen-alone to prevent heart disease, heart attacks, or dementia
- Using estrogen-alone may increase your chance of getting cancer of the uterus (womb)
- Using estrogen-alone may increase your chances of getting strokes or blood clots
- Using estrogen-alone may increase your chance of getting dementia, based on a study of women age 65 years or older
- You and your healthcare provider should talk regularly about whether you still need treatment with PREMARIN or PREMPRO

PREMARIN and PREMPRO should be used at the lowest effective dose and for the shortest duration consistent with treatment goals and risks. If you use or are considering PREMARIN or PREMPRO only to treat menopausal changes or dryness, itching, and burning in or around the vagina, talk with a healthcare provider about whether a topical vaginal product would be better for you. If you use or are considering PREMARIN or PREMPRO only to prevent osteoporosis

due to menopause, talk with your healthcare provider about whether a different treatment or medicine without estrogens would be better for you.

Do not take PREMARIN or PREMPRO if you have unusual vaginal bleeding; currently have or have had cancer of the breast or uterus; had a stroke or heart attack; currently have or have had blood clots; currently have or have had liver problems; have been diagnosed with a bleeding disorder; are allergic to any of their ingredients; or think you may be pregnant. In general, the addition of a progestin is recommended for women with a uterus to reduce the chance of getting cancer of the uterus.

In a clinical trial, the most commonly reported (≥5%) side effects that occurred more frequently with PREMARIN than with placebo were vaginitis due to yeast or other causes, vaginal bleeding, painful menstruation, and leg cramps.

In a clinical trial, the most common side effects (≥5%) that occurred with PREMPRO were vaginal bleeding, vaginitis due to yeast or other causes, painful menstruation, breast enlargement, breast pain, and leg cramps.

Please see full prescribing information including boxed warnings on www.premarin.com and www.prempro.com.

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