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Pfizer Recognizes 10th Anniversary Of The Women's Health Initiative: A Modern Day Perspective On Hormone Therapy

Ongoing Analyses have Helped Re-evaluate Benefit-Risk Profile of Hormone Therapy for Appropriate Menopausal Women

NEW YORK, N.Y., July 9 - Pfizer Inc. (NYSE:PFE), one of the world's leading biopharmaceutical companies, offering a portfolio of hormone therapy treatments - including PREMPRO[®] (conjugated estrogens/ medroxyprogesterone acetate tablets) and PREMARIN[®] (conjugated estrogens tablets, USP) - today recognizes the 10th anniversary of the initial release of data from the landmark Women's Health Initiative (WHI) study, one of the largest clinical trials of women's health undertaken in the U.S.

Ongoing analyses of data from the WHI have helped the scientific community re-evaluate the benefits and risks of hormone therapy, giving healthcare providers and women an opportunity to discuss hormone therapy as a treatment option for menopausal symptoms.

The WHI was designed to investigate preventive benefits and risks of hormone therapy, measuring outcomes such as cardiovascular disease, cancer and osteoporosis. It did not evaluate the primary uses of estrogen-alone and estrogen-plus-progestin for the relief of moderate-to-severe menopausal symptoms, for which the medicines are indicated. The hormone therapy trials of estrogen-plus-progestin and estrogen-alone were stopped in July 2002 and March 2004, respectively, when the trials surpassed the limit set by the investigators for the particular benefits and risks being studied. Following the reporting of these results, millions of women stopped taking hormone therapy to alleviate their menopausal symptoms or opted against initiating treatment.

Thousands of women begin menopause every day in the U.S. - many of whom will suffer from potentially debilitating, moderate-tosevere symptoms. The FDA considers hormone therapy the most effective FDA-approved medicine for the relief of hot flashes, night sweats and vaginal dryness, a position supported by leading professional medical societies, including the North American Menopause Society, the Endocrine Society and the International Menopause Society.

"No one menopause treatment is right for every woman. If and how to treat menopausal symptoms is a decision that depends on factors such as a woman's age, time since the onset of menopause, symptom severity and whether she has had a hysterectomy," said Gail Cawkwell, M.D., Ph.D., vice president, medical affairs, Pfizer. "All women deserve to have comprehensive conversations with their healthcare providers about their menopause experience that include an informed, balanced discussion of all available treatment options, including hormone therapy."

The science-based guidance in the package inserts of all hormone therapy products advises healthcare providers to prescribe the medicine at the lowest effective dose and for the shortest duration consistent with treatment goals and risks for the individual woman.

-2-

About the Women's Health Initiative

The WHI was a 15-year research program conducted by the National Institutes of Health (NIH). The hormone therapy trial was designed to investigate the benefits and risks of estrogen-plusprogestin therapy (PREMPRO) and estrogen-alone therapy (PREMARIN) among 27,347 postmenopausal women 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

PREMARIN and PREMPRO were selected to be studied in the WHI by the NIH because they were the most frequently prescribed postmenopausal hormone therapy products in the United States.

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 (\geq 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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