

October 19, 2010

Pfizer Statement Regarding *Journal of the American Medical Association (JAMA)* Analysis “Estrogen Plus Progestin and Breast Cancer Incidence and Mortality in Postmenopausal Women”

NEW YORK – Pfizer Inc. today commented on Dr. Rowan Chlebowski et al.’s analysis of data from the observational follow-up to the randomized estrogen plus progestin arm of the Women’s Health Initiative (WHI), which appears in JAMA’s October 20, 2010, issue. While the Company is still reviewing the data, it offers the following initial response.

“As a science-based company, we take this analysis seriously. It is important to view the data in the full context of both the symptoms of menopause as well as the extensive body of information – developed over more than 60 years – on the known benefits and risks of hormone therapy.

“It is well known that for some women, moderate to severe symptoms of menopause such as hot flashes and night sweats can be very debilitating. The medical community has long encouraged women experiencing such symptoms to discuss the benefits and risks of various treatment options with their doctors.

“As to its risks, hormone therapy is among the most thoroughly studied medicines and the increased risk of breast cancer compared to placebo has been included in Prempro’s label since its introduction in 1995. This analysis does not alter that risk, nor does it dispute hormone therapy’s effectiveness. FDA describes hormone therapy as ‘the most effective FDA approved medicine for relief of hot flashes [and] night sweats.’

“Further, most studies examining hormone therapy and breast cancer mortality conflict with the conclusions of this analysis. As Dr. Chlebowski et al. state in this analysis, ‘most but not all observational studies have suggested that breast cancers associated with combined post-menopausal hormone therapy have favorable characteristics, less advanced stage, and less mortality risk.’

“We stand behind the current, science-based guidance in Prempro’s label, which advises doctors to prescribe the medicine at the ‘lowest effective dose and for the shortest duration consistent with treatment goals and risks for the individual woman’ and patients to ‘talk regularly’ with their healthcare provider about whether treatment is still appropriate for them.”

Both Premarin (conjugated estrogens tablets USP), approved by the FDA in 1942, and Prempro (conjugated estrogens/medroxyprogesterone acetate tablets), approved by the FDA in 1994, are used for the treatment of moderate to severe symptoms of menopause and the prevention of osteoporosis.

The data that appear in JAMA do not pertain to women who have undergone hysterectomies and are taking Premarin alone.

See full prescribing and patient information including boxed warning at www.prempro.com.

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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 PREMPRO or PREMPHASE

PREMARIN (conjugated estrogens tablets, USP) is used 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 your chances of getting osteoporosis (thin weak bones).

PREMPRO is used after menopause to reduce moderate to severe hot flashes, to treat menopausal changes in and around the vagina, and to help reduce your chances of getting osteoporosis (thin, weak bones). Do not take PREMPRO if you have had your uterus (womb) removed (hysterectomy).

PREMARIN and PREMPRO should be used at the lowest effective dose and for the shortest duration consistent with your treatment goals and risks. If you use or are considering PREMARIN or PREMPRO only to treat your menopausal changes or

dryness, itching, and burning in or around your vagina, talk with your 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; 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 ($\geq 5\%$) that occurred with PREMPRO were vaginal bleeding, vaginitis due to yeast or other causes, painful menstruation, breast enlargement, breast pain, and leg cramps.