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**Pfizer Response To Global Consensus Statement On  
Menopausal Hormone Therapy**

NEW YORK, N.Y., March 15 - The Global Consensus Statement on Menopausal Hormone Therapy (the Statement), published today in *Climacteric* and *Maturitas*, is an important addition to the ongoing discussion about the safety and efficacy profile of hormone therapy for appropriate menopausal women.

Pfizer applauds the efforts of the seven signatories to produce core, globally-recognized recommendations with regard to menopausal hormone therapy. These organizations - which represent the leading global health organizations focused on women's health and menopause in their respective regions around the world - include the American Society for Reproductive Medicine, the Asia Pacific Menopause Federation, The Endocrine Society, the European Menopause and Andropause Society, the International Menopause Society, the International Osteoporosis Foundation and the North American Menopause Society.

"This global consensus statement provides much needed clarity for women who are suffering from menopause-related symptoms," said Gail Cawkwell, M.D., Ph.D., vice president, medical affairs, Pfizer. "These straightforward and evidence-based recommendations from major regional menopause societies are the result of the scientific community's efforts to reevaluate hormone therapy."

### **About Menopausal Hormone Therapy**

The Global Consensus Statement on Menopausal Hormone Therapy (MHT), which can be found [here](#), states that 'MHT is the most effective treatment for vasomotor symptoms associated with menopause at any age, but benefits are more likely to outweigh risks for symptomatic women before the age of 60 years or within 10 years after menopause.'

The benefit-risk profile of hormone therapy is well-established for the treatment of moderate-to-severe vasomotor symptoms. As the Statement notes, 'the option of MHT is an individual decision in terms of... health priorities as well as personal risk factors.' Estrogen-alone therapy can increase the chance of developing cancer of the uterus in nonhysterectomized women. Adding a progestin reduces this risk. Boxed warnings in product labeling note that the Women's Health Initiative estrogen-plus-progestin substudy reported increased risks of pulmonary embolism, deep vein thrombosis (DVT), stroke, invasive breast cancer, and myocardial infarction. All estrogen therapy products also carry a boxed warning for increased risk of DVT and stroke.

Pfizer offers a portfolio of menopausal hormone therapy treatments - including PREMARIN<sup>®</sup> (conjugated estrogens tablets, USP), PREMPRO<sup>®</sup> (conjugated estrogens/medroxyprogesterone acetate tablets) and PREMARIN (conjugated estrogens) VAGINAL CREAM<sup>®</sup>.

As with any prescription medication, the decision to initiate hormone therapy - and the route of administration - should be made in close collaboration with a healthcare provider, carefully weighing the patient's risk factors, including lifestyle and family medical history. The 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.

**IMPORTANT SAFETY INFORMATION**

Using estrogen-alone may increase your chance of getting cancer of the uterus (womb). Report any unusual vaginal bleeding right away. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.

Do not use estrogens, with or without progestins, to prevent heart disease, heart attacks, strokes or dementia (decline in brain function). Using estrogens, with or without progestins, may increase your chance of getting dementia, based on a study of women 65 years of age or older.

Using estrogen-alone may increase your chances of getting strokes or blood clots. Using estrogens with progestins may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots.

You and your healthcare provider should talk regularly about whether you still need treatment with PREMARIN, PREMPRO or PREMARIN VAGINAL CREAM.

PREMARIN, PREMPRO or PREMARIN VAGINAL CREAM should not be used if you have unusual vaginal bleeding; have or had cancer; had a stroke or heart attack; have or had blood clots or liver problems; have a bleeding disorder; are allergic to any of the ingredients; or think you may be pregnant.

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. Common side effects of **PREMARIN VAGINAL CREAM** include headache, pelvic pain, breast pain, vaginal bleeding and vaginitis.

#### INDICATIONS

PREMARIN and PREMPRO are 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 the chances of getting osteoporosis (thin weak bones). **PREMARIN VAGINAL CREAM** is used after menopause to treat menopausal changes in and around the vagina and to treat painful intercourse caused by these changes.

If you are using or are considering using **PREMARIN** or **PREMPRO** only to treat symptoms of vaginal dryness, consider topical therapies first. If you are using or are considering using **PREMARIN** or **PREMPRO** only to prevent osteoporosis due to menopause, talk with your health care professional about whether a different treatment or medicine without estrogens might be better for you.

***Please see full prescribing information including boxed warnings on [www.PREMARIN.com](http://www.PREMARIN.com), [www.PREMPRO.com](http://www.PREMPRO.com) and [www.PREMARINVAGINALCREAM.com](http://www.PREMARINVAGINALCREAM.com).***

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