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**FOR IMMEDIATE RELEASE**

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**New Guidelines Confirm the Clinical Value of Hormone Therapy for Treatment of Menopausal Symptoms and Protection of Bone Health**

*ACOG and Other Leading Medical Organizations Provide Evidence-Based Guidance for Women and Physicians*

**Madison, N.J., October 5, 2004** – In a comprehensive new report, The American College of Obstetricians and Gynecologists’ (ACOG) Hormone Therapy Task Force confirms that estrogens and estrogens plus progestins are “highly effective” in relieving postmenopausal vasomotor symptoms, are the “most effective treatment” for severe symptoms, and may be an appropriate “first choice of therapy” for the prevention of osteoporosis in women with menopausal symptoms.

According to Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), the ACOG report adds to the evidence-based consensus among leading women’s health experts regarding the important role of estrogen and estrogen plus progestin (as hormone therapy, or HT) in the treatment of vasomotor symptoms

and the prevention of postmenopausal osteoporosis. The Task Force report is published in the October 1 issue of the *Journal of Obstetrics & Gynecology*.

According to the report authors, “Oral estrogens alone or estrogens plus progestins are highly effective for the alleviation of hot flashes and night sweats.” In addition, hormone therapy “is an effective antiresorptive agent for preventing postmenopausal bone loss.”

“These latest guidelines from ACOG represent a balanced view of the overall clinical evidence regarding the appropriate role of postmenopausal hormone therapy,” says Gary L. Stiles, M.D., Executive Vice President and Chief Medical Officer, Wyeth Pharmaceuticals. “We are pleased that the guidelines are consistent with the prescribing information for both PREMARIN<sup>®</sup> and PREMPRO<sup>™</sup>, and reinforce the use of hormone therapy for its approved indications—the relief of moderate to severe menopausal symptoms such as hot flashes, night sweats, and vaginal dryness, and the prevention of postmenopausal osteoporosis.”

The benefits and risks of HT should be discussed in detail with each patient before initiating therapy. The FDA, Wyeth, and leading women’s health experts recommend hormone therapy be prescribed at the lowest effective dose for the shortest duration consistent with treatment goals and risks for the individual woman. A number of lower doses of PREMARIN and PREMPRO<sup>™</sup>

(conjugated estrogens/medroxyprogesterone acetate tablets) are now widely available.

“The report also states that for the prevention of chronic diseases in postmenopausal women, such as heart disease and cognitive decline, that the risks outweigh the benefits,” adds Stiles. “However, for women with menopausal symptoms who wish to protect their bone health by preventing osteoporosis—also a chronic condition—it is very clear from this report that hormone therapy may be an excellent first-line therapy.”

Up to 20 percent of a woman’s expected lifetime bone loss can occur in the years immediately following menopause. Today, over 30 million American women of menopausal age are at risk for osteoporosis and low bone mass, characterized by fragile bones and fracture susceptibility. It is estimated that by 2010, this number will grow to more than 35 million women. At an annual public health cost of more than \$17 billion as of 2001, osteoporosis and low bone mass are major public health concerns. Later this month, the Surgeon General of the United States is expected to release its first report on osteoporosis and bone diseases in this country.

The ACOG report also states that studies show bone mineral density can be maintained with HT doses lower than those used in the past. The report follows additional evidence-based guidance previously issued by other respected women’s health organizations, including the North American Menopause Society

(NAMS) and the American Society for Reproductive Medicine (ASRM), which also support the postmenopausal symptom relief and bone protection provided by hormone therapy.

Wyeth provides an online resource – ([www.estrogeninfo.com](http://www.estrogeninfo.com)) – where clinicians and women can get more information on hormone therapy via links to a variety of authoritative sources, including ACOG, NAMS, and ASRM.

### **About the PREMARIN Family of Products**

Wyeth Pharmaceuticals is the leader in women's health with a long history of product innovation. Its low dose hormone therapies are part of a family of well-studied products, which includes multiple strengths of PREMARIN and PREMPRO. Currently taken by over 4 million women in the United States alone, these products are prescribed more often than any other brand of postmenopausal hormone therapy.

**What is the most important information a woman should know about PREMARIN (estrogens) or PREMPRO (a combination of estrogens and a progestin)?**

- **Estrogens increase the chances of getting cancer of the uterus.**

**A woman should report any unusual vaginal bleeding right away while taking these products. Vaginal bleeding after menopause may be a**

**warning sign of cancer of the uterus (womb). Her health care 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.**

**Using estrogens with or without progestins may increase a woman's chances of getting heart attacks, strokes, breast cancer, and blood clots.**

**Using estrogens, with or without progestins, may increase a woman's risk of dementia, based on a study of women age 65 years or older. A woman and her health care provider should talk regularly about whether she still needs treatment with estrogens.**

PREMARIN is used after menopause to reduce moderate to severe hot flashes; to treat moderate to severe dryness, itching, and burning in or around the vagina; and to help reduce a woman's chances of getting osteoporosis (thin, weak bones).

PREMPRO is used after menopause in women with a uterus to reduce moderate to severe hot flashes; to treat moderate to severe dryness, itching, and burning in or around the vagina; and to help reduce a woman's chances of getting osteoporosis (thin, weak bones).

PREMARIN and PREMPRO should be used at the lowest effective dose and for the shortest duration consistent with a woman's treatment goals and risks. If

using PREMARIN or PREMPRO only to treat a woman's symptoms of vaginal dryness, consider topical therapies first. If a woman does not have symptoms, non-estrogen treatments should be carefully considered before taking PREMARIN and PREMPRO solely for the prevention of postmenopausal osteoporosis.

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

In a clinical trial, the most commonly reported ( $\geq 5\%$ ) side effects that occurred more frequently with PREMPRO 0.45 mg/1.5 mg and PREMPRO 0.625 mg/2.5 mg were breast pain/enlargement, vaginitis due to yeast or other causes, leg cramps, vaginal spotting/bleeding, and painful menstruation. In a clinical trial, there was no difference in the commonly reported ( $\geq 5\%$ ) side effects for women taking PREMPRO 0.3 mg/1.5 mg compared to those taking placebo.

PREMARIN and PREMPRO should not be used if a woman has unusual vaginal bleeding, has or had cancer of the breast or uterus, had a stroke or heart attack in the past year, has or had blood clots, has liver problems, is allergic to any of the ingredients in PREMARIN or PREMPRO, or thinks she may be pregnant. In general, the addition of a progestin is recommended for women with a uterus.

### **About Wyeth**

Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), has leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology and vaccines. Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

*The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events that involve risks and uncertainties including, without limitation, risks associated with the inherent uncertainty of pharmaceutical research, product development, manufacturing, commercialization, economic conditions including interest and currency exchange rate fluctuations, changes in generally accepted accounting principles, the impact of competitive or generic products, trade buying patterns, wars or terrorist acts, product liability and other types of lawsuits, the impact of legislation and regulatory compliance and obtaining reimbursement, favorable drug pricing, access and other approvals, environmental liabilities, and patent, and other risks and uncertainties, including those detailed from time to time in the Company's periodic reports, including current reports on Form 8-K, quarterly reports on Form 10-Q and the annual report on Form 10-K, filed with the Securities and Exchange Commission. Actual results may vary materially from the forward-looking statements. The Company assumes no obligation to publicly*

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