Pfizer Inc. Affirms Confidence In Its Hormone Therapy Medicines As Important Treatment Options

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(BUSINESS WIRE)--In connection with the New York Times' recent coverage of hormone therapy1, Pfizer Inc. today released important facts and context to respond to the newspaper's account. Pfizer believes the coverage is based on a misleading and selective reading of both the science and history of hormone therapy (HT) medicines.

Premarin (conjugated estrogens tablets USP) and Prempro (conjugated estrogens/medroxyprogesterone acetate tablets), which are approved by the Food and Drug Administration (FDA), have brought relief to tens of millions of women for decades. The FDA has stated that HT has a well-established safety profile and is among the most studied classes of medicines. In addition, the FDA states that HT "is the most effective FDA approved medicine for relief of hot flashes, night sweats or vaginal dryness."

A full, fair and accurate report on HT would show:

1. FDA-approved hormone therapy is an important treatment option for certain post-menopausal women.

First and most importantly, doctors have been prescribing HT medicines for the treatment of menopausal symptoms (e.g., hot flashes and night sweats), as well as for the prevention of post-menopausal osteoporosis, for decades. As FDA itself wrote in a news release following the Women's Health Initiative study (WHI): "Because there are few alternatives for the relief of severe vasomotor symptoms and severe symptoms of vulvar vaginal atrophy, estrogens and estrogens with progestins have an important role in

women's health." The FDA has regularly and thoroughly reviewed the benefits and risks of these medicines, and has consistently determined that the benefits outweigh the risks for the appropriate woman.

2. Wyeth has acted responsibly by studying its hormone therapy medicines closely, including the risk of breast cancer, for decades.

HT medicines are among the most thoroughly studied drugs. Wyeth conducted or supported more than 180 studies covering 180,000 women that examined the risks and benefits of hormone therapy (including the WHI), 19 of which expressly examined hormone therapy and breast cancer risk. The first such study was published in 1959, and these studies were published in peer-reviewed medical journals and were consistent with the then-current medical science.

The most definitive study on hormone therapy and breast cancer, the WHI, reaffirmed the increased relative risk of breast cancer that was already in the labeling for Premarin and Prempro.

3. The labels for Premarin and Prempro, which are the official, FDA-approved description of their benefits and risks relied upon by doctors, are and have been accurate and science-based, and have warned of the risk of breast cancer for many years.

Guidance to use Premarin and Prempro at the lowest dose and for the shortest duration needed to meet treatment goals has been included in the labels of these medicines for decades.

Breast cancer risks were discussed at least nine times in the 1995 launch label for Prempro, and have been included in the Premarin label for decades. The label and the Physicians’ Desk Reference in which it is included carry the most authoritative information on a medicine’s risks and benefits.

Moreover, commenting on the Prempro labeling before the WHI, Janet Woodcock, then-director of FDA's Center for Drug Evaluation and Research, told the NIH on October 24, 2002: "What was known at the time about benefits and risks was discussed within that label."

After the WHI study, Wyeth proactively updated its label and worked with the FDA to develop labeling that reflected the medical community's new understanding of risks associated with hormone therapy. The FDA wrote in a January 8, 2003, press release: "The revisions for the Premarin, Prempro, and Premphase labeling build on revisions to

the labeling that Wyeth Pharmaceuticals (the products' manufacturer) made in August 2002, shortly after the release of the findings from WHI. Since August, FDA has carefully reviewed the data from the WHI study and has worked with Wyeth to develop the new labeling approved today for these products."

Similarly, in response to numerous studies that Wyeth and others conducted that reported increased risks of endometrial carcinoma associated with Premarin in the 1970s, the company included a prominent warning of those risks in the Premarin label seven months before the FDA issued class labeling.

About Premarin and Prempro

Both Premarin (conjugated estrogens tablets USP), approved by the FDA in 1942, and Prempro (conjugated estrogens/medroxy-progesterone acetate tablets USP), approved by the FDA in 1994, treat moderate to severe symptoms of menopause and help reduce the chances of osteoporosis.

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1 Estrogens prescribed for women without uteruses and estrogens with progestins prescribed for women with uteruses for the treatment of certain menopausal symptoms and the prevention of post-menopausal osteoporosis

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