New Phase 3 Safety Data For Bazedoxifene/Conjugated Estrogens, An Investigational Therapy Being Studied For The Treatment Of Menopausal Symptoms, Show Less Than One Percent Incidence Of Endometrial Hyperplasia

Wednesday, September 21, 2011 - 10:30pm

Data assessing breast density demonstrate no statistically significant difference compared with placebo at one year Data found postmenopausal non-hysterectomized women with bothersome hot flashes and sleep problems experienced a statistically significant improvement in sleep parameters and health-related quality of life compared with placebo at one year

(BUSINESS WIRE)--Pfizer Inc. will announce new one-year results from the Selective estrogens, Menopause, And Response to Therapy [SMART]-5 Phase 3 study of the safety and efficacy of the investigational tissue selective estrogen complex (TSEC) bazedoxifene/conjugated estrogens (BZA/CE) at the 22nd annual meeting of the North American Menopause Society (NAMS), September 21-24 in Washington, D.C. BZA/CE is being developed by Pfizer for the treatment of moderate-to-severe hot flashes, vulvar and vaginal atrophy and the prevention of osteoporosis in women following menopause. SMART-5 was a one-year study that investigated over 1,800 postmenopausal women who

had not had a hysterectomy. The study was designed to assess the safety and efficacy of two doses of BZA/CE treatment on the endometrial lining of the uterus and evaluate the efficacy of BZA/CE for the prevention of osteoporosis (results recently presented on September 16 at the American Society of Bone and Mineral Research meeting in San Diego, Calif.). All primary and secondary endpoints in SMART-5 were met. The most common adverse effects seen in women treated with BZA/CE in SMART-5 were back pain, inflammation of the nose and throat and headache.

These data provide new insights about BZA/CE. The blended tissue selective activity of the components of a TSEC – a selective estrogen receptor modulator paired with one or more estrogens - is believed to yield different clinical results than those provided by the components alone. BZA/CE was not shown to increase vaginal bleeding, breast density or breast pain when compared to placebo in SMART-5.

It is hypothesized that BZA/CE could provide a new treatment option for symptomatic postmenopausal women with a uterus.

About SMART-5

SMART-5 was a Phase 3 double-blind, placebo-controlled study conducted to evaluate the efficacy and safety of BZA/CE, CE/ medroxyprogesterone acetate (MPA), and BZA monotherapy all compared with placebo in 1,843 non-hysterectomized, postmenopausal women. Subjects were randomized to receive daily oral doses of BZA 20 mg/CE 0.45 mg (n=335), BZA 20 mg/CE 0.625 mg (n=368), BZA 20 mg (n=169), CE 0.45 mg/MPA 1.5 mg (n=149), or placebo (n=354). Specifically, the study investigated the effect of two dose strengths of BZA/CE on the incidence of endometrial hyperplasia (primary endpoint), prevention of postmenopausal osteoporosis (primary endpoint), bone mineral density, breast density, sleep parameters and health-related quality of life (secondary endpoints) at the end of one year of treatment.

In SMART-5, endometrial safety was evaluated by the incidence of endometrial hyperplasia as measured by endometrial biopsy at one year. Results indicate that BZA 20 mg/CE 0.45 mg and BZA 20 mg/CE 0.625 mg demonstrated less than one percent incidence of endometrial hyperplasia over 12 months. Breast tenderness associated with BZA/CE was similar to that of placebo. Bleeding and spotting with BZA/CE was similar to placebo.

The effects of BZA/CE on breast density over 12 months were also evaluated in 940 postmenopausal women with a uterus. Subjects were randomized to receive two doses of BZA/CE [BZA 20 mg/CE 0.45 (n=231), BZA 20 mg/CE 0.625 mg (n=247)], BZA 20 mg

(n=122) and CE 0.45 mg/MPA 1.5 mg (n=100), or placebo (n=240). Results of this analysis indicate that women treated with BZA 20 mg/CE 0.45 or BZA 20 mg/CE 0.625 mg for 12 months showed no statistically significant differences in breast density compared with those treated with placebo.

In another SMART-5 sub-study, the effects of BZA/CE on sleep parameters and health-related quality of life (HR-QoL) were evaluated in 459 postmenopausal non-hysterectomized women with bothersome vasomotor symptoms and sleep problems at baseline. Subjects were randomized to BZA 20 mg/CE 0.45 (n=115) or BZA 20 mg/CE 0.625 mg (n=123), BZA 20 mg (n=49), CE 0.45 mg/MPA 1.5 mg (n=56), or placebo (n=116) daily for 12 months. Using a validated quality of life measurement tool, women treated with BZA/CE had statistically significant improvement in sleep parameters and health-related quality of life at one year compared with placebo.

About BZA/CE

BZA/CE contains a selective estrogen receptor modulator (SERM), bazedoxifene, and conjugated estrogens. It is being investigated for treatment of moderate-to-severe menopausal symptoms such as hot flashes and night sweats, vulvar and vaginal atrophy, and for the prevention of postmenopausal osteoporosis.

About Menopause

It is estimated that approximately 43 million women in the United States are of menopausal age, i.e., between the ages of 40 and 59. Of these women, 17 million experience vasomotor symptoms and 9 million experience moderate-to-severe symptoms. The majority of menopausal women experiencing moderate to severe vasomotor symptoms are not currently treating their symptoms.

Pfizer medicines help women manage different aspects of their health throughout their lives. These treatments go beyond menopause medicines to include all aspects of health throughout a woman’s life, such as reproductive and maternal health, vaccines, nutrition, vitamins and bone health. In addition, Pfizer is working to better understand how the evolving healthcare landscape is impacting women, and how we can support their unique needs, now and in the future.

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discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at http://www.pfizer.com.

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This release contains forward-looking information about an investigational therapy, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such investigational therapy as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8-K.

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