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European Medicines Agency Accepts Regulatory Submission For Bazedoxifene/Conjugated Estrogens For The Treatment Of Symptoms Associated With Menopause And Osteoporosis

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced that the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for bazedoxifene/conjugated estrogens (BZA/CE), a potential new medicine for postmenopausal women with a uterus for the treatment of estrogen deficiency symptoms and treatment of osteoporosis in women at risk of fracture. Pfizer expects a decision from the European Commission in 2013.

BZA/CE pairs the selective estrogen receptor modulator (SERM) bazedoxifene with conjugated estrogens. BZA/CE has been studied in a Phase III clinical development program (**S**elective estrogens, **M**enopause **A**nd **R**esponse to **T**herapy [SMART] trials) which included approximately 7,500 postmenopausal women and assessed the safety and efficacy of BZA/CE for the treatment of estrogen deficiency symptoms, such as moderate-to-severe hot flashes and vulvar and vaginal atrophy, as well as postmenopausal osteoporosis. The most common adverse drug reactions observed in the SMART trials were abdominal pain, vaginal yeast infection and muscle spasms.

“We are pleased to be one step closer to potentially bringing bazedoxifene/conjugated estrogens to women to help manage symptoms of menopause,” said Steve Romano, senior vice president, Head of the Medicines Development Group in Pfizer’s Primary Care Business Unit. “This milestone is a further example of the company's commitment to advance treatments that may help improve health and well-being at each stage of life.”

About Menopause

Menopause is a normal, natural event - it marks the permanent end of fertility and is usually confirmed when a woman has missed her period for 12 consecutive months (in the absence of other obvious causes). Menopause is associated with reduced functioning of the ovaries due to aging, resulting in lower levels of estrogen and other hormones. In the European Union, an estimated 67 million women are of menopausal age. Of those, approximately 75% suffer from hot flashes.

About Osteoporosis

Osteoporosis is a disease of the bones that leads to an increased risk of fracture. Decreased estrogen levels are associated with rapid bone loss, making women more susceptible to osteoporosis. Osteoporosis is estimated to affect up to a fifth of women in Europe between the ages of 50 and 79.

About the Ligand/Pfizer Collaboration

BZA/CE was developed by Wyeth and was part of a broader research collaboration with Ligand Pharmaceuticals Incorporated on SERMs. Pfizer acquired the rights to BZA/CE when it acquired Wyeth. Under the terms of the agreement, Ligand receives certain payments and royalties from Pfizer on predetermined development and sales milestones.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the 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 www.pfizer.com.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of July 19, 2012. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties about an investigational therapy, bazedoxifene/conjugated estrogens (BZA/CE), including its potential benefits, that is under review by regulatory authorities in the European Union (EU). Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when regulatory authorities in the EU will approve the Marketing Authorization Application for BZA/CE 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, 2011 and in its reports on Form 10-Q and Form 8-K.

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