U.S. Food And Drug Administration (FDA) Accepts New Drug Application For Bazedoxifene/Conjugated Estrogens, An Investigational Treatment For Symptoms Associated With Menopause And Prevention Of Osteoporosis

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) and Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) today announced that the United States Food and Drug Administration (FDA) accepted for review a New Drug Application (NDA) for bazedoxifene/conjugated estrogens (BZA/CE), a potential new medicine for non-hysterectomized women for the treatment of moderate-to-severe vasomotor symptoms (VMS) and vulvar and vaginal atrophy (VVA) associated with menopause, as well as the prevention of postmenopausal osteoporosis. The FDA Prescription Drug User Fee Act (PDUFA) date is October 3, 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 (Selective estrogens, Menopause And Response to Therapy [SMART] trials), which included approximately 7,500 postmenopausal women and assessed the safety and efficacy of BZA/CE for the treatment of moderate-to-severe VMS and VVA associated with menopause, as well as the prevention of postmenopausal osteoporosis. The most common adverse drug reactions observed in the SMART trials were abdominal pain, vaginal yeast infection and muscle spasms.

“Pfizer is dedicated to advancing treatments that may help improve health and well-being at each stage of life,” said Gail Cawkwell, M.D., Ph.D., vice president, Pfizer’s Medical Affairs. “BZA/CE was developed for non-hysterectomized women with moderate-to-severe menopausal symptoms. This milestone moves us one step closer towards potentially providing the first new treatment option in the U.S. in years for the treatment of these women’s menopausal symptoms.”

BZA/CE was developed by Wyeth Pharmaceuticals and was part of a broader research collaboration with Ligand on SERMs. Pfizer acquired the rights to BZA/CE when it acquired Wyeth.

“Pfizer continues to make good progress with this program, with this NDA submission shortly following the European Marketing Authorization Application submission earlier this year,” said John Higgins, president and chief executive officer, Ligand. “This is an important therapeutic need, and we commend Pfizer for its continued strong commitment to the program.”

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. Menopause is associated with reduced functioning of the ovaries due to aging, resulting in lower levels of estrogens and other hormones. 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.

About Osteoporosis

Osteoporosis is a disease of the bones that leads to an increased risk of fracture. Decreased estrogen levels at the time of menopause are associated with rapid bone loss, making women more susceptible to osteoporosis. About 60 percent of women 50 years of age or older have low bone mass or osteoporosis.

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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 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.

About Ligand Pharmaceuticals

Ligand is a biopharmaceutical company that develops and acquires assets it believes will generate royalty revenues and, under its lean corporate cost structure, produce sustainable profitability. Ligand has a diverse asset portfolio addressing the unmet medical needs of patients for a broad spectrum of diseases including thrombocytopenia, multiple myeloma, diabetes, hepatitis, muscle wasting, dyslipidemia, anemia, and osteoporosis. Ligand’s Captisol® platform technology is a patent protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Ligand has established multiple alliances with the world's leading pharmaceutical companies including GlaxoSmithKline, Merck, Pfizer, Eli Lilly & Company, Baxter International, Bristol-Myers Squibb, Celgene, Onyx Pharmaceuticals, Lundbeck Inc., and The Medicines Company, among others. Please visit www.captisol.com for more information on Captisol. For more information on Ligand, please visit www.ligand.com.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of December 13, 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 U.S. and the EU. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when regulatory authorities in the U.S. and the EU will approve our applications 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.

LIGAND DISCLOSURE NOTICE: This news release contains certain forward-looking statements by Ligand that involve risks and uncertainties and reflect Ligand's judgment as of the date of this release. These statements include those related to the investigational therapy, including its potential benefits, that is under review by regulatory authorities in the United States (US). Actual events or results may differ from Ligand’s or Pfizer’s expectations. For example, there can be no assurance that bazedoxifene/conjugated estrogens or any product in the Ligand or Pfizer pipelines will be successfully developed, that any of the milestone triggers will be achieved, that regulatory approvals will be granted, that patient and physician acceptance of these products will be achieved, that final results of human clinical trials will be consistent with any interim results, that final results will be supportive of regulatory approvals required to market products or that any revenue will be achieved from this partnered program. The failure to meet expectations with respect to any of the foregoing matters may reduce Ligand's stock price. Additional information concerning these and other risk factors affecting Ligand's business can be found in prior press releases available via www.ligand.com as well as in Ligand's public periodic filings with the Securities and Exchange Commission at www.sec.gov. Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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