Pfizer Logo

Pfizer Receives FDA Complete Response Letter for Lasofoxifene

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(BUSINESS WIRE)--Pfizer Inc said today it has received a complete response letter from the U.S. Food and Drug Administration (FDA) asking for additional information on the company's application for lasofoxifene. The investigational compound is currently under review for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Pfizer is reviewing the letter and will work with FDA to determine the appropriate next steps regarding the company's application.

Pfizer submitted the current application for lasofoxifene on December 18, 2007. On September 8, 2008, an FDA scientific advisory panel voted 9-3 (with one abstention) that there is a population of postmenopausal women with osteoporosis in which the benefits of lasofoxifene likely outweigh the risks. FDA is not required to follow the advice of the panel.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency issued a positive opinion on December 18, 2008, recommending marketing authorization for lasofoxifene. The CHMP's opinion will be reviewed by the European Commission, which has authority to approve medicines for the European Union.

About Lasofoxifene

Lasofoxifene is a selective estrogen receptor modulator, or SERM, in the same chemical class as raloxifene. With its high affinity for estrogen receptors, lasofoxifene acts as an agonist in bone and as an antagonist in the breast. Thus, it modulates the estrogen receptor in a different manner than estrogen, which accounts for the effects of lasofoxifene observed in multiple target tissues.

DISCLOSURE NOTICE: The information contained in this release is as of January 16, 2009. Pfizer assumes no obligation to update any 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 regarding a product candidate that is under review by the United States Food and Drug Administration (FDA) and the European Commission (EC) . Such risks and uncertainties include, among other things, whether and when the FDA and the EC will approve the product candidate, their decisions regarding labeling and other matters that could affect its availability or commercial potential, as well as competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and in its reports on Form 10-Q and Form 8-K.

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