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Lilly Resolves Investigation of Its Evista Marketing and Promotional Practices

Company Accepts One Misdemeanor Charge Related to Evista Promotion in 1998

INDIANAPOLIS, Dec 21, 2005 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY), the Department of Justice's Office of Consumer Litigation and the U.S. Attorney's Office for the Southern District of Indiana have reached a settlement of the previously reported government investigation into Lilly's Evista marketing and promotional practices. As part of the settlement, Lilly has agreed to plead guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act. The plea is for the off-label promotion of Evista during 1998. The government has not, however, charged the company with any unlawful intent, nor does Lilly acknowledge any such intent. The settlement is subject to approval by the federal court in Indianapolis; the company anticipates a hearing on the settlement will occur within the next few weeks.

This investigation commenced in July 2002 and has resulted in the government alleging that, during 1998, certain Lilly employees promoted Evista for the prevention and reduction in the risk of breast cancer and cardiovascular risk reduction. The product is not approved by the U.S. Food and Drug Administration for either of these uses, although both uses are the subject of large, multi-year registration clinical trials that began in the late 1990s. Evista is approved in the U.S. for both the prevention and treatment of osteoporosis in post-menopausal women.

"We deeply regret the 1998 conduct, which has resulted in a federal misdemeanor charge," said Sidney Taurel, chairman and chief executive officer for Lilly. "We take seriously our responsibilities to abide by all the laws governing our business practices and are committed to ensuring our employees' actions reflect the highest legal and ethical standards of conduct. Although the government has not charged Lilly with any unlawful intent, we will continue to take steps designed to assure that Lilly's promotional activities remain fully compliant."

In addition to the misdemeanor charge, the government has filed a civil complaint alleging similar Evista-related conduct continued into 2000. The company disagrees and has not admitted to these allegations. However, the company has agreed to settle the dispute over these allegations in order to reach a final resolution of this investigation.

In connection with the overall settlement, Lilly has agreed to pay a total of \$36 million. As previously reported, Lilly took a charge in the fourth quarter of 2004 in connection with this investigation. The 2004 charge was sufficient to cover this settlement payment; consequently, no further charge will be taken by the company.

In addition, as part of the settlement, a civil consent decree will require Lilly to continue to have a compliance program and to undertake a set of defined corporate integrity obligations related to Evista for five years. Lilly has implemented and continues to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that its marketing and promotional practices comply with promotional laws and regulations. Lilly's compliance program includes the elements of compliance guidelines issued by the Department of Health and Human Services, Office of Inspector General, for the pharmaceutical industry. The company has a vice president and chief compliance officer, who reports directly to Taurel and the Board of Directors; corporate compliance committee; a code of conduct; policies and procedures specific to promotion and marketing; extensive training; auditing, monitoring and reporting programs including a compliance hotline; and disciplinary and corrective action processes.

In a separate investigation previously disclosed by the company, the U.S. Attorney's Office for the Eastern District of Pennsylvania informed Lilly that a whistleblower action under the civil False Claims Act has been filed in that District, alleging that the company engaged in certain unlawful marketing practices related to Evista. That office advised Lilly that, contingent on the court's acceptance of today's announced settlement, it has no current plans to pursue further action on Evista and will close the Evista portion of its ongoing investigation.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers -- through medicines and information -- for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com. C-LLY

This press release contains forward-looking statements about the expected resolution of the previously reported government investigation into Lilly's Evista marketing and promotional practices. The settlement is subject to court approval and therefore

there can be no guarantee that it will be concluded. Additionally, while this settlement will resolve the claims brought by these government agencies in this investigation, it does not preclude other parties from bringing claims based on similar or different allegations. For additional information about the factors that affect the company's business, please see Exhibit 99 to the company's latest Form 10-Q filed November 2005. The company undertakes no duty to update forward-looking statements.

Evista(R) (raloxifene hydrochloride, Lilly)

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