Lilly Resolves Investigations of Past Zyprexa Marketing and Promotional Practices

Company Accepts One Misdemeanor Charge Related to Zyprexa Promotion Between 1999 and 2001

INDIANAPOLIS, Jan 15, 2009 /PRNewswire-FirstCall via COMTEX News Network/ --

Eli Lilly and Company (NYSE: LLY) today announced that it has reached resolution with the United States Attorney for the Eastern District of Pennsylvania (EDPA) and the Office of Consumer Litigation of the Department of Justice regarding the previously-reported government investigation into the company's past U.S. marketing and promotional practices for the antipsychotic medication Zyprexa(R) (olanzapine).

Lilly has been cooperating with the government in its investigation since it began in 2004. As part of the resolution, Lilly has agreed to plead guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act. The company will also enter into a settlement agreement resolving the federal government's civil investigation. Even though the company disagrees with and does not admit to the civil allegations, the company has agreed to settle the dispute over these allegations. In addition, the company has agreed to settle civil investigations brought by the State Medicaid Fraud Control Units of the states that have coordinated with the EDPA in its investigation.

"We deeply regret the past actions covered by the misdemeanor plea," said John C. Lechleiter, Ph.D., chairman, president and chief executive officer of Lilly. "At Lilly we take seriously our responsibilities to abide by all the laws governing our business practices, and we realize that we have a tremendous responsibility to the patients and healthcare professionals we serve. Every day and with every interaction we strive to operate in a responsible and compliant manner. Doing the right thing is non-negotiable at Lilly, and I remain personally committed to all of us at Lilly maintaining the highest standards of conduct."

Continued Lechleiter, "The company's comprehensive compliance program is an embedded part of our company's culture. These are not just words to us - we continue to implement a range of programs and policies to help ensure that we operate in a manner consistent with all applicable laws and regulations. These programs apply to all parts of our business, and all of our employees are aware of the imperative for them to be models of compliance and of ethical behavior."

The misdemeanor plea is for the off-label promotion of Zyprexa between September of 1999 and March of 2001. Specifically, the plea states that Lilly promoted Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia, although Zyprexa is not approved for such uses. As part of this agreement regarding the criminal investigation, Lilly has agreed to pay $615 million.

Under terms for the resolution of the civil investigations, Lilly has agreed to make payments totaling nearly $800 million. Approximately $438 million will be paid to the federal government and approximately $362 million will be made available for payment to settling states. As previously reported, Lilly took a charge of $1.415 billion, or $1.29 per share, in the third quarter of 2008 in connection with this investigation. The 2008 charge will be sufficient to cover the payments announced today. The company is now finalizing the tax treatment of these payments, and will communicate this impact when the company announces fourth quarter 2008 financial results on January 29, 2009.

Lilly has a comprehensive compliance program that is designed to ensure that the company's global business practices fully comply with all laws and regulations. Lilly's compliance program, which the company is committed to continually improving and enhancing, includes each of 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 Lilly's chief executive officer; a 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 processes for disciplinary and corrective action.

Also, as part of the settlement, Lilly has entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS). This agreement will require Lilly to maintain its compliance program and to undertake a set of defined corporate integrity obligations for five years. The terms of the corporate integrity agreement are largely consistent with the company's existing compliance program. They also provide for an independent third-party review organization to assess and report on the company's systems, processes, policies, procedures and practices. This agreement reflects Lilly's commitment to continually build on a foundation of compliance, accuracy and transparency.

The settlement is subject to approval by the federal court in Philadelphia; the company anticipates a hearing on the settlement will occur within the next few weeks.

Zyprexa Background

Zyprexa is indicated in the United States for the short- and long-term treatment of schizophrenia, acute mixed or manic episodes of bipolar I disorder, and maintenance treatment of bipolar disorder. Since Zyprexa was introduced in 1996, it has been prescribed for an estimated 26 million patients around the world. Zyprexa is not approved for patients under 18 years of age.

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Zyprexa is not approved for the treatment of patients with dementia-
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related psychosis. Elderly patients with dementia-related psychosis
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treated with atypical antipsychotic drugs are at an increased risk of
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death compared with those patients taking a placebo.
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In addition, compared to elderly patients with dementia-related psychosis taking a placebo, there was a significantly higher incidence of cerebrovascular adverse events in elderly patients with dementia-related psychosis treated with Zyprexa.

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including Zyprexa.

While relative risk estimates are inconsistent, the association between atypical antipsychotics and increases in glucose levels appears to fall on a continuum and olanzapine appears to have a greater association than some other atypical antipsychotics. Physicians should consider the risks and benefits when prescribing olanzapine to patients with an established diagnosis of diabetes mellitus, or who have borderline increased blood glucose levels. Patients taking olanzapine should be monitored regularly for worsening of glucose control. Persons with risk factors for diabetes who are starting on atypical antipsychotics should undergo baseline and periodic fasting blood glucose testing. Patients who develop symptoms of hyperglycemia during treatment should undergo fasting blood glucose testing.

Undesirable alterations in lipids have been observed with olanzapine use. Clinical monitoring, including baseline and follow-up lipid evaluations in patients using olanzapine, is advised. Significant, and sometimes very high, elevations in triglyceride levels have been observed with olanzapine use.

Potential consequences of weight gain should be considered prior to starting olanzapine. Patients receiving olanzapine should receive regular monitoring of weight.

As with all antipsychotic medications, a rare and potentially fatal condition knows as Neuroleptic Malignant Syndrome NMS has been reported with Zyprexa. If signs and symptoms appear, immediate discontinuation is recommended. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

Also, as with all antipsychotic treatments, prescribing should be consistent with the need to minimize Tardive Dyskinesia (TD). The risk of developing TD and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Other potentially serious adverse events include low blood pressure, seizures, elevated prolactin levels, elevated liver enzymes, cognitive and motor impairment, body temperature elevation, and trouble swallowing.

The most common treatment-emergent adverse event associated with Zyprexa in placebo-controlled, short-term schizophrenia and bipolar mania trials was somnolence. Other common events were dizziness, weight gain, personality disorder (COSTART term for nonagressive objectionable behavior), constipation, akathisia, postural hypotension, dry mouth, asthenia, dyspepsia, increased appetite and tremor.

Full prescribing information, including a boxed warning, is available at www.zyprexa.com.

About Lilly

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 that are based on management's current expectations, but actual results may differ materially due to various factors. The company cannot guarantee court approval of the settlement. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. The company's results may also be affected by such factors as competitive developments affecting current products; rate of sales growth of recently launched products; the timing of anticipated regulatory approvals and launches of new products; regulatory actions regarding currently marketed products; other regulatory developments and government investigations (including state claims relating to Zyprexa that are not resolved in this settlement); patent disputes and other litigation involving current and future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; changes in tax law; asset impairments and restructuring charges; acquisitions and business development transactions; and the impact of exchange rates. For additional information about the factors that affect the company's business, please see the company's latest Form 10-Q filed November 2008. The company undertakes no duty to update forward-looking statements.

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Zyprexa(R) (olanzapine, Lilly)

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