Lilly to Take Charge to Earnings Related to Pending Federal and State Investigations of Past Practices

Company Will Take $1.415 Billion Charge in Third Quarter 2008

INDIANAPOLIS, Oct 21, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) today announced that it is in advanced discussions to resolve the ongoing investigations led by the U.S. Attorney's Office for the Eastern District of Pennsylvania (EDPA) related to past U.S. marketing and promotional practices for its antipsychotic medication Zyprexa(R) (olanzapine). As a result, the company will record in the third quarter of 2008 a charge of $1.415 billion, or $1.29 per share.

The Government's investigation is related to past marketing and promotional practices for Zyprexa in the United States. Lilly has now incorporated an enhanced compliance program that is designed to ensure that the company's global marketing and promotional practices fully comply with all 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 Lilly's chief executive officer; 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.

"Lilly's compliance programs are comprehensive and demonstrate that compliance is a top priority of the company," said Robert A. Armitage, Lilly's senior vice president and general counsel. "The government's investigation of Zyprexa has been ongoing for five years and we now have a heightened sense of responsibility to all our stakeholders to intensify efforts to resolve these issues. Moving our discussions with the government forward is a step towards focusing us on delivering quality, innovative medicines to serve unmet medical needs," he added.

In March 2004, the EDPA advised Lilly that it had commenced an investigation related to the company's U.S. marketing and promotional practices with respect to Zyprexa, Prozac(R), and Prozac Weekly(TM). In November 2007, Lilly received a grand jury subpoena from the EDPA for a broad range of documents related to Zyprexa. In addition, the State Medicaid Fraud Control Units of more than 30 states are coordinating with the EDPA in its investigation of any Medicaid-related claims relating to the marketing and promotion of Zyprexa. Eleven other states (Louisiana, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, West Virginia, Connecticut, Arkansas and Idaho) have filed lawsuits over Zyprexa and are not participating in the coordinated investigation.

The charge reflects the company's currently estimable exposure with respect to these matters. If the ongoing discussions are successfully concluded, the company expects that they would settle the Zyprexa-related federal claims, as well as similar Medicaid-related claims of states participating in the settlement. The company continues to cooperate with the government in these matters.

Separately, Lilly announced on October 7, 2008, that it had resolved a multi-state investigation under the consumer protection laws of 32 states and the District of Columbia (DC) related to the sales, marketing and promotion of Zyprexa for $62 million. In March, Lilly entered into a $15 million settlement with the State of Alaska, which concluded an ongoing trial involving various issues surrounding Zyprexa.

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.

Zyprexa is not approved for the treatment of patients with dementia-related psychosis. Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared with those patients taking a placebo. 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.

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 that we will reach a settlement of the matters discussed above, or that the settlement will be on the terms or for the amount anticipated. 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 the settlement under discussion); 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 August 2008. The company undertakes no duty to update forward-looking statements.

Zyprexa(R) (olanzapine, Lilly)

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