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Lilly Responds to the Cost-Effectiveness Analysis of the CATIE Schizophrenia Trial

Among the atypicals, Zyprexa found to be most cost-effective

INDIANAPOLIS, Dec 01, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company commented today on findings from the cost-effectiveness analysis (CEA) of the Clinical Antipsychotic Trial of Intervention Effectiveness (CATIE). The data was published in the December 1 issue of The American Journal of Psychiatry.

The objective of the CATIE CEA was to determine whether the first drug to which patients were randomized in phase 1 of CATIE resulted in differences in cost-effectiveness over the entire study. The primary outcomes used to measure cost-effectiveness in the 18-month analysis were total healthcare costs (medication cost plus health services use, such as hospital stays and outpatient services) and Quality Adjusted Life Years (QALYs).

According to the CATIE CEA, perphenazine, a first-generation typical, was found to be the most cost-effective treatment when used in modest doses in the treatment of patients without pre-existing Tardive Dyskinesia (TD), followed closely by Zyprexa(R) (olanzapine). Among the atypicals studied Zyprexa was found to be the most cost-effective. These results are a secondary analysis to the initial findings of CATIE, which showed that Zyprexa was one of the most effective antipsychotic medications studied, with Zyprexa-treated patients staying on their medication longer and requiring fewer hospitalizations as reported in phase 1.

Cherri Miner, MD, Lilly U.S. Medical Director for Zyprexa said, "Lilly supports studies such as CATIE that add to the body of knowledge for enhancing the treatment of schizophrenia. However, as in every study or analysis, there are limitations that need to be recognized and understood. For example, the data was limited by a high drop-out rate and an inability to capture longer-term effects, and there was a need to statistically adjust for prior hospitalization because patients with prior hospitalizations are more likely to be hospitalized in the future. Most importantly, the CATIE Cost Effectiveness Analysis findings with respect to perphenazine are specific to a unique patient group -- that is, schizophrenia patients treated with perphenazine at modest doses without pre-existing tardive dyskinesia. Therefore, the relevance of these findings to other typical antipsychotics is unknown as is the relevance to patients with pre-existing tardive dyskinesia, since they were not given perphenazine. It also is difficult to determine the clinical relevance of the perphenazine findings given how infrequently it is currently prescribed in the United States.

"In addition, we agree with the study's authors that cost-effectiveness analyses can inform policy discussions, but they should not necessarily translate into recommendations for clinical care or healthcare policy. While cost may be one of the considerations, it is not necessarily the only priority. Choosing a medication that will quickly and effectively reduce a patient's symptoms is of utmost importance. It is important for doctors and patients to have access to the entire spectrum of treatment options to find the medication that works best for each patient."

Other CATIE CEA findings included:

- * Among the atypicals studied (Zyprexa, quetiapine, risperidone, and ziprasidone), Zyprexa had the lowest total healthcare costs. Zyprexa was less costly by about \$2,700 per year than quetiapine, \$1,212 per year less than risperidone, and \$3,564 per year less than ziprasidone.
- * Despite being -- prior to enrollment in the study -- the costliest patient group, with the highest rate of prior inpatient hospitalizations, the Zyprexa group showed the largest decrease in total average monthly healthcare cost during the study.

CATIE Background

CATIE was designed to evaluate the overall clinical effectiveness of antipsychotics in the treatment of schizophrenia, as measured by any-cause medication discontinuation, a measure that integrates both the patients' and the doctors' judgment of how well a medication works, its safety and how well the patient tolerates the treatment.

In both CATIE 1 and 2, the dose range for Zyprexa was 7.5-30mg/day, which is outside of the current FDA approved labeling of 5-20mg/day.

CATIE found that for Zyprexa the average time to discontinuation was 9.2 months as compared with 4.6 months for quetiapine, 4.8 months for risperidone, 3.5 months for ziprasidone and 5.6 months for perphenazine. The differences were statistically significant for olanzapine compared with risperidone and quetiapine, but not for perphenazine or ziprasidone.

Patients taking Zyprexa also experienced fewer hospitalizations for schizophrenia than patients taking other medications. Total PANSS scores improved over time in all groups, and patients taking Zyprexa had greater initial improvement.

The authors of CATIE phase 1 also noted that patients taking Zyprexa experienced greater weight gain and increases in measures of glucose and lipid metabolism versus patients using other antipsychotics that were studied. Information about adverse events related to increases in blood glucose levels, lipid metabolism and weight gain is included in the Zyprexa product label. For patients who discontinued treatment due to adverse events, more patients taking Zyprexa discontinued because of weight gain and metabolic events.

Zyprexa Background

Zyprexa is indicated in the United States for the short- and long-term treatment of schizophrenia, acute mixed and manic episodes of bipolar I disorder, and maintenance treatment of bipolar disorder. Since Zyprexa was introduced in 1996, it has been prescribed to approximately 20 million people worldwide.

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.

Prescribing should be consistent with the need to minimize the risk of neuroleptic malignant syndrome, tardive dyskinesia, seizures and orthostatic hypotension.

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 nonaggressive 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.

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