Alert for Healthcare Professionals

Ziprasidone (marketed as Geodon)

9/2006: The issue described in this alert has been addressed in product labeling.

FDA Alert [4/11/2005]: Increased Mortality in Patients with Dementia-Related Psychosis

FDA has determined that patients with dementia-related psychosis treated with atypical (second generation) antipsychotic medications are at an increased risk of death compared to placebo. Based on currently available data, FDA has requested that the package insert for Geodon be revised to include a black box warning describing this risk and noting that this drug is not approved for this indication.

This information reflects FDA's current analysis of all available data concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of Protopic, please contact the FDA MedWatch program at 1-800-FDA-1088 or http://www.fda.gov/medwatch/report/hcp.htm

Data Summary

- Analyses of seventeen placebo controlled trials that enrolled 5106 elderly patients with dementia related behavioral disorders revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Clinical trials were performed with Zyprexa (olanzapine), Abilify (aripiprazole), Risperdal (risperidone), and Seroquel (quetiapine). Over the course of these trials averaging about 10 weeks in duration, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature.
- While FDA's analyses only included studies conducted in the four drugs mentioned above, the consistent findings across studies (a numerical increase in mortality in the drug-treated groups was seen in a total of fifteen of the seventeen studies), and across all three relevant chemical classes support the view that this signal is likely applicable to all atypical antipsychotic drugs.