Updated Safety Information for ZYPREXA® (olanzapine) in Elderly Dementia Patients, Announced in Canada - Eli Lilly Canada Inc.

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Contact: Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)

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Public Advisory
Health Canada Endorsed Important Safety Information on ZYPREXA® (olanzapine)

Subject: Updated Safety Information for ZYPREXA® (olanzapine) in Elderly Dementia Patients, Announced in Canada

Toronto, March 18, 2004 - Further to discussions with Health Canada, Eli Lilly Canada Inc. has recently informed healthcare professionals of new safety information on Zyprexa® (olanzapine) concerning strokes and related events in elderly patients with dementia-related psychosis. Zyprexa is not approved for the treatment of elderly patients with dementia-related psychosis.

Information from five clinical studies in elderly patients with dementia-related psychosis showed that a higher proportion of patients taking Zyprexa experienced strokes or related events than did those who received placebo (sugar pill).

Please note that there is insufficient information to determine whether stroke in elderly patients with dementia-related psychosis is associated specifically with Zyprexa or all antipsychotic agents.

Patients are reminded of risk factors associated with an increased risk for stroke include previous history of stroke, high blood pressure, smoking, and medical conditions and/or medications that have an association with stroke. Generally, there is an increased risk of stroke and stroke-like events in the elderly population.

Patients or their caregivers should immediately report to their healthcare professional any signs and/or symptoms of potential stroke such as sudden weakness or numbness in the face, arms, or legs, and/or speech or vision problems. Patients or their caregivers should inform their healthcare professional of their past and present medical history and should also consult their healthcare professional prior to making any changes to their medication.

Information about this safety update has been sent to doctors and pharmacists to ensure they are aware of this new safety information when prescribing and dispensing Zyprexa. Eli Lilly Canada Inc. is working with Health Canada to update the Canadian Prescribing Information for Zyprexa.

Zyprexa is approved in Canada for the treatment of schizophrenia and related psychotic disorders and acute bipolar mania and to date, 13 million patients worldwide have been treated with Zyprexa for these approved treatments.

Inquiries from patients and healthcare professionals should be directed to the Eli Lilly Canada Customer Response Centre at 1-888-545-5972 between 8 a.m. and 6 p.m. EST. For media inquiries, please contact Kent Hovey-Smith, Eli Lilly Canada Inc. at (416) 693-3879.

Any suspected adverse reactions in patients receiving Zyprexa (olanzapine) can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
Health Canada
