

Olanzapine Study F1D-MC-HGAP
Patient Summary

Serious Adverse Event, Marked Abnormality:
Vital Sign, ECG

Patient Number 001-1002
Study Medication: Olanzapine
Age: 52
Origin: Caucasian

Dose: 10 mg/day
Sex: Male
Weight: 93.89 kg

EVENT: Actual Term: Schizophrenic reaction
COSTART Term: Schizophrenic reaction
Severity: Moderate
Onset: 3-NOV-93, day 40 of therapy

Serious?: Yes
Expectancy?: Expected
1639 Filed?: Yes

Causality?: Not applicable
If "Yes," List Mfr. US93110706A
Control No.:

Days of Therapy: 24-SEP-93 - 3-FEB-95, 497 days (patient is ongoing)

Actions: Hospitalization 4-NOV-93 - 5-NOV-93
Historical Illnesses: Post Traumatic Stress Disorder, Cerebrovasculat accident, Hepatitis
Secondary Conditions: Delusions, Hallucinations, Hypercholesterolemia, Hypertryglyceridemia, Tardive dyskinesia
Other Adverse Events: Increased depression (15-JUL-94 - 22-JUL-94)
Increased paranoid (3-SEP-93 - 29-OCT-93)
New onset diabetes mellitus (18-JAN-94 - Ongoing) —
Insomnia (15-NOV-94 - Ongoing)
Increased Agitation (3-SEP-93 - 29-OCT-93)
Laboratory Abnormalities: 27-JAN-94 - Glucose non-fasting = 16.431 mmol/L
Concomitant Medications: Ativan 1 to 4 mg QD PRN (6-SEP-93 to 21-OCT-93)
Temazepam 30mg QD/BID (20-NOV-93 to 30-NOV-93)
Glyburide 1.25 mg QD (11-MAR-94 to ongoing)

Summary:

Patient 1002 voluntarily admitted himself to a psychiatric hospital on 4-NOV-93 because of a schizophrenic reaction. He was discharged the next day after having been treated with Haldol 5mg, Artane 2mg, Thorazine 50mg and Depakote 250mg on 4-NOV-93. He was hospitalized again on 8-FEB-94 due to an exacerbation of schizophrenic reaction. Patient was hospitalized on 27-MAY-94 due to a subjective exacerbation of symptoms including suspiciousness, auditory hallucinations and some unusual beliefs. The schizophrenic reaction abated on 24-JAN-94 after the patient had been discharged from the hospital on 15-JUN-94. One month later the patient was hospitalized again due to an increase of depressive feelings and an exacerbation of schizophrenia; these symptoms abated on 22-JUL-94. On 20-NOV-94 the patient was hospitalized due to an insidious return of delusional thinking, auditory hallucinations and insomnia. The patient had also been hospitalized on 20-JAN-94 after a lab test performed on that day showed a blood sugar level of 363 mg/ml. The patient had no previous history of diabetes was reported to have gained weight during the study. *and therefore a diagnosis of diabetes mellitus was established. EKG otherwise*
In addition, an ECG performed on 27-AUG-93 showed a sinus tachycardia but it was considered within normal limits. When repeated at the end of the acute phase (24-SEP-93), it was considered normal. When performed during the open label phase on 27 JAN 94 it was normal. At visit 316 (19-AUG-94), a prolongation of the QRS interval to 0.1 second was noted but, overall the results were still considered

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*and 27 JAN 94
Date incorrect?*

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within normal limits. Finally, patient's baseline weight measured on 2-SEP-93 was 88.45 Kg but it increased by 6.8 Kg on 3-DEC-93, by 8.6 Kg on 28-DEC-93, by 6.8 Kg on 25-FEB-94 and by 6.3 Kg on 29-MAR-94 to ~~return to~~ 85.3 Kg at visit 319 (3-FEB-95).

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