Synopsis – Study 12009A

Title of Study

A prospective, open-label, single-arm, multi-national, multi-centre, flexible-dose, extension study of the SCoP 99824 with sertindole for patients suffering from schizophrenia

Investigators

8 investigators at 8 centres in France

Signatory investigator – Professor Joseph Peuskens, Saint Jozef University, Kortenberg, Belgium

Study Centres

8 centres in France

Publications

None (as of the date of this report)

Study Period

First patient first visit – 28 November 2007

Last patient last visit – 26 July 2010

Objectives

- *Primary objective*:
  - to permit the sertindole-treated patients who completed SCoP Study 99824 to continue with their sertindole treatment in countries where sertindole is not yet adequately available
- *Secondary objective*:
  - to monitor the serious adverse events (SAEs) during treatment with sertindole under normal conditions of use

Methodology

- This was a multi-national, multi-centre, open-label, one-arm, flexible-dose study in patients with schizophrenia who had completed Study 99824 (Sertindole Cohort Prospective [SCoP] study).
- Sertindole was prescribed according to usual practice and in accordance with the EU Summary of Product Characteristics (SPC).
- The patients were assessed and managed by the investigators in accordance with routine clinical practice.
- Patient visits were scheduled every 3 months.
- A Safety Follow-up Visit was scheduled for 30 days after completion of the study or after withdrawal from the study.

Number of Patients Planned and Analysed

- Approximately 50 patients were planned for enrolment.
- Patient disposition is tabulated below:

	Sertindole n
Patients treated:	18
Patients completed	10
Patients withdrawn	8
Reason for withdrawal:	
Serious adverse event	1
Lack of efficacy	2
Non-compliance with IMP	1
Other	4

Diagnosis and Main Inclusion Criteria Patients with schizophrenia who, in the investigator's judgement, needed to continue their sertindole treatment after having completed the SCoP Study
Investigational Medicinal Product, Dose and Mode of Administration *Sertindole* – daily dose in accordance with the EU SPC; tablets, 4 mg, 12 mg, 16 mg, 20 mg, orally
Duration of Treatment Approximately 32 months or until sertindole became available on the market
Safety Assessments • SAEs • Vital status
Statistical Methodology Descriptive statistics were applied.
Demography of Study Population The study included 5 women and 13 men with a mean age of 42 years (range: 22 to 61 years).
Safety Results • The mean exposure to sertindole was 400 days and the mean dose of sertindole was 14 mg/day. • No patients died • Two patients had SAEs: – A [redacted] woman had been treated with sertindole for nearly 6.5 years when she, during investigations for constipation, was diagnosed with increased liver enzymes (*hepatic cytolysis*). The patient was withdrawn from the study. The patient refused having follow-up laboratory tests taken; clinically she recovered. – A [redacted] man had been treated with sertindole for approximately 6.5 years when he was hospitalised with pneumonia and diverticulosis of the sigmoid colon. Following antibiotic treatment for the pneumonia, he recovered and was discharged. The patient continued treatment with sertindole in the study.
Conclusions In this extension to the SCoP Study, 18 patients were included to allow them continued treatment with sertindole. No new safety issues were raised in this study. The low number of patients does not allow for any safety conclusions to be drawn.
Date of the Report 3 January 2011
This study was conducted in compliance with the principles of *Good Clinical Practice*.