SYNOPSIS *ANNEX I*

Name of Sponsor/Company: Hannover Medical School, Prof. Dr. med. Stefan Bleich, Department of Psychiatry, Social Psychiatry and Psychotherapy, Carl-Neuberg-Str. 1, 30625 Hannover, Germany	**Individual Study Table Referring to Part of the Dossier**	*(For National Authority Use only)*
Name of Finished Product: Seroquel Prolong ®	**Volume:**	
Name of Active Ingredient: Quetiapine	**Page:**	

Title of Study:
Effects of Quetiapine XR in schizophrenic patients with cannabis abuse and/or cannabis induced psychosis.

Investigators: Dr. Dillo PI, Hannover Medical School, Prof. Dr. Schneider PI, Krankenhaus Lübbecke, Dr. Sander, Klinikum Wahrendorff

Study centre(s): Hannover Medical School, Krankenhaus Lübbecke, Klinikum Wahrendorff

Publication (reference)
none

Studied period (years):	**Phase of development:**
17/09/2009-13/07/2010 **(date of first enrolment) - (date of last completed)**	**2008-2009**

Objectives:
Primary objective: To evaluate the effect of quetiapine on positive and negative symptoms of schizophrenia on schizophrenic patients associated with cannabis abuse and patients with psychotic disorders through cannabis abuse
Secondary objectives: (i) change of craving, (ii) change of CGI values, (iii) change of depression, anxiety and sleep disturbances, and (iv) safety and tolerability of Quetiapine XR (Seroquel Prolong®) extended-release

Methodology:
Multicenter, single arm, open-label, non-randomized, phase III trial

Number of patients (planned and analysed):
30 planned,
4 included (2 drop out)

Diagnosis and main criteria for inclusion:
Schizophrenia

Main inclusion criteria:
- Females and/or males aged 18 to 60 years.
- Provision of written informed consent. In case of acute psychosis written informed

consent has to be obtained from the legal representative of the patient, if applicable or from two independent physicians not involved in the study. When the patient recovers, the written informed consent has to be signed by the patient itself.

- A diagnosis of schizophrenia (ICD10: F20.0, F20.1, F20.2, F20.4, F20.5) with associated cannabis abuse and/or psychotic disorders (e.g. schizophrenia) through cannabis (ICD 10: F12.5, F12.7)
- A score of at least 15 on the positive scale of the PANSS.

Test product, dose and mode of administration, batch number:

Quetiapine 200-800mg oral

Duration of treatment:

12 weeks

Reference therapy, dose and mode of administration, batch number:

none

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Criteria for evaluation:
The effect of Quetiapine on positive and negative symptoms of schizophrenia with associated cannabis abuse or patients with psychotic disorders through cannabis is measured with PANSS within 3 months. Assessment of craving (by means of visual analogue scale), quality and patterns of sleep (PSQI), CGI values and depressive and anxiety state (by means of Hamilton A and D scales) and EuropASI after 3 months participation in the study.

Descriptive analysis of safety parameters

Statistical methods:
The planned number of 30 subjects could not be recruited. Only 2 patients completed the treatment according to the study protocol. A conclusive statistical analysis is not possible.

SUMMARY - CONCLUSIONS
The planned number of 30 subjects could not be recruited during the estimated recruitment phase. The recruitment frequency was considerably lower than expected. The clinical trial is an Investigator Initiated Trial (IIT) with limited funds.

EFFICACY RESULTS:
Only 2 patients completed the treatment according to protocol. Thus, no conclusive efficacy results can be concluded.

SAFETY RESULTS:
No SAE was observed in the patients which were recruited to the study. The few available data do not indicate a change in the risk-benefit assessment of the IMP as given initially at the launch of the study.

CONCLUSION:
The planned number of 30 subjects could not be recruited. Only 2 patients completed the treatment according to the study protocol. A conclusive analysis is not possible.

Date of the report 23.02.2011

Date of premature Termination of the Trial: 25.08.2010