

## STUDY REPORT SUMMARY

### ASTRAZENECA PHARMACEUTICALS

**FINISHED PRODUCT:** None

**ACTIVE INGREDIENT:**

<b>Study No:</b> NCT00984373
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<b>Epidemiological study to describe approaches in diagnosis, treatment and social functioning of schizophrenic patients in Bulgaria</b>
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**Developmental Phase:** Non-Interventional Study

**Study Completion Date:** 30/11/2009

**Date of Report:** 29/10/2010

#### Number of patients and sites

Total 440 patients all over Bulgaria were enrolled as planned. Patient enrolment took place between September and December 2009.

This is a purely observational study; therefore patients are not assigned to a particular therapeutic strategy beforehand by a protocol. Treatment is according to current clinical practice.

The overall Aim for this Non-Interventional Study (NIS) was to provide accurate, reliable information on schizophrenia clinical management in order to detect unmet medical needs of this disease in terms of patient characteristics and diagnostic and treatment approaches: initial and subsequent.

#### OBJECTIVES:

a. Descriptive objectives:

Regarding the patient

- To describe schizophrenia patient characteristics: demographics, educational level, employment status, occupation
- To describe the clinical history of disease: type of schizophrenia, age of onset, duration of untreated illness, psychiatric and somatic co-morbidities and relevant medical history.
- To describe the process of care: circumstances leading to the current contact with health institution, hospital stays, route and type of pharmacotherapy, concomitant therapy for somatic diseases

b. Analytical objectives:

- To identify factors associated with the different levels of functional and social integration status.

#### Study design

Multicentre, non-interventional, cross-sectional study.

## Study Flow-chart

The study consisted of one visit.

## Patient population

First 5 schizophrenia patients above 18 years of age attending the doctor's office in two consecutive days. Written informed consent was required for inclusion in the study

## METHODS:

First 5 schizophrenia patients attending the doctor's office in two consecutive days and who have provided informed consent.

All patients regardless of whether they are participating in clinical trials or not were eligible to be included in the study. This is a purely observational study, therefore participation in this study will not interfere with participation in a clinical trial.

## Statistical Analysis

A descriptive analysis approach was used to analyse schizophrenic population, clinical history of disease and process of care.

## RESULTS:

This is a purely descriptive study, showing that most of the patients are diagnosed with F20.0 Paranoid schizophrenia (95.0%).

Most of the patients are in the active age groups between 26 and 60 years of age (a total of about 85%). Men and women are almost equally presented.

In almost half of the patients (48.2%) the onset of the disease has been with an acute episode of schizophrenia. In the active stage the paroxysmal-progressive course is the most common one (59.5%). The average age at onset is 28 years and the duration of the untreated disease is about an year and a half.

Accompanying psychiatric disorders have not been seen in 94.8%, while in 71.8% have not been seen accompanying somatic diseases. The leading one among the somatic diseases is the arterial hypertension (14.1%).

Family history was reported in 30% of the patients. It is most commonly related to parents and/or siblings (a total of 18.1%).

As general, the patient has visited the physician on his own (61.6%). Not infrequently he has been brought by a relative (34.8%). The average number of hospitalizations since diagnosis is 6.3, varying from 0 to 53. The average number of visits per year is 0.7, varying from 0 to 8. Most commonly the patients have been on oral treatment with an atypical antipsychotic (52.4%). The treated with a depot-medication have almost always been prescribed a classic antipsychotic (93.9%).

The present treatment is most commonly with an atypical antipsychotic (73.1%). Of the other medications, the depot-preparations are used in 9.8%.

The most widely used of the classic antipsychotics is haloperidol, which is being prescribed in 63% of the cases of treatment with an oral classic antipsychotic.

With regards to the currently used oral atypical antipsychotics, there is no a definitively preferred one. The most commonly recommended one (in about 24%) is quetiapine,

followed by olanzepine (in about 21%). Among the rest the medications, but prescriber more rarely, are clozapine (in about 15%) and risperidone (12.5%).

The treatment practice shows that at present most commonly (in about 83% of the cases) an oral atypical antipsychotic is being used.