AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECAPHARMACEUTICALS

FINISHED PRODUCT: Casodex
ACTIVE INGREDIENT: Bicalutamide

Study No: NIS-OHR-CAS-2008/1

Developmental phase: Non-interventional study
Study Completion Date: 02/2010
Date of Report:01/2011.

OBJECTIVES:

Primary Objective:

Primary objective was to evaluate PSA level at the end of the study (after 7-9 months of bicalutamide therapy)

Secondary Objective:

- to describe bicalutamide prescribing practice based on prostate cancer stage
- to evaluate PSA level after 4-12 weeks of bicalutamide therapy
- to asses time to disease progression based on PSA values
- to evaluate percentage of patients with disease progression
- to evaluate withdrawals due to adverse events
- to evaluate withdrawals due to Croatian Institute for Health Insurance guidelines for bicalutamide prescription

METHODS:

Patient population

This study enrolled male patients aged 40 years and older with diagnosis of advanced prostate cancer (outpatients or hospitalized) who are already treated with bicalutamide for at least 4 weeks and maximum 12 weeks in combination with medical or surgical castration according to standard clinical practice

Design

This study was non-interventional, 6-month, observational, prospective, non-comparative, epidemiological study. Descriptive statistics will be used for evaluation of collected data.

Study was conducted by 34 urologists and oncologists.

This non-interventional study had two study visits.

Each PCP enrolled 5-20 consecutive patients with on bicalutamide therapy for at least 4 weeks and maximum 12 weeks.
When patients with diagnosis of advanced prostate cancer visited PCP, the study details were explained to patient and he was asked to sign the Informed Consent in line with local regulations.
During the visits investigator filled in Case Report Forms (CRF) with the data obtained from the interview as well as from patient's medical records.

There were three scheduled visits: at inclusion, 4-6 weeks after first visit and 12-14 weeks after first visit. The time between the scheduled visits was determined according to standard clinical practice in Croatia.
During each visit, investigators filled in Case Report Forms for each patient with history data, previous therapy, date of introduction of bicalutamide, PSA level (at the time of visit), evaluation of disease since the initiation of therapy with bicalutamide (according to PSA and clinical status) and further therapy with bicalutamide.

Table 1. Study plan

	Visit 1	*Visit 2*
Date of the visit	X	X
Date of signing ICF	X	
Date of birth	X	
History data:		
- date of diagnosis	X	
- present status of disease a. local PC b. Locally advanced PC c. Metastatic PC	X	
- TNM status and date	X	
- GLEASON status and date	X	
- Last PSA level and date (at the time of bicalutamid introduction, if applicable)	X	
- Levels of hepatics enzymes (at the time of bicalutamid introduction, if applicable)	X	
Previous therapy		
- prostatectomy (yes/no) and date	X	
- radiotherapy (yes/no) and date	X	
- surgical castration (yes/no) and date	X	

- LHRH therapy – drug and dose - antiandrogen hormonal therapy – drug and dose - chemotherapy - Other (related to primary disease)	X X X X X	
Date of introduction of bicalutamide	X	
PSA level (at the time of visit)	X	X
Evaluation of disease since the initiation of therapy with bicalutamide (according to PSA and clinical status) - improvement - stable disease - progressive disease	X	X
AE (reported according to the requirements for spontaneo AE reporting in Croatia	X	X
Further therapy with bicalutamide - yes - no (reason for discontinuation) - death - Croatian Institute for Health Insurance guidelines for bicalutamide prescription - Other	X	X

Study Drug
Bicalutamide

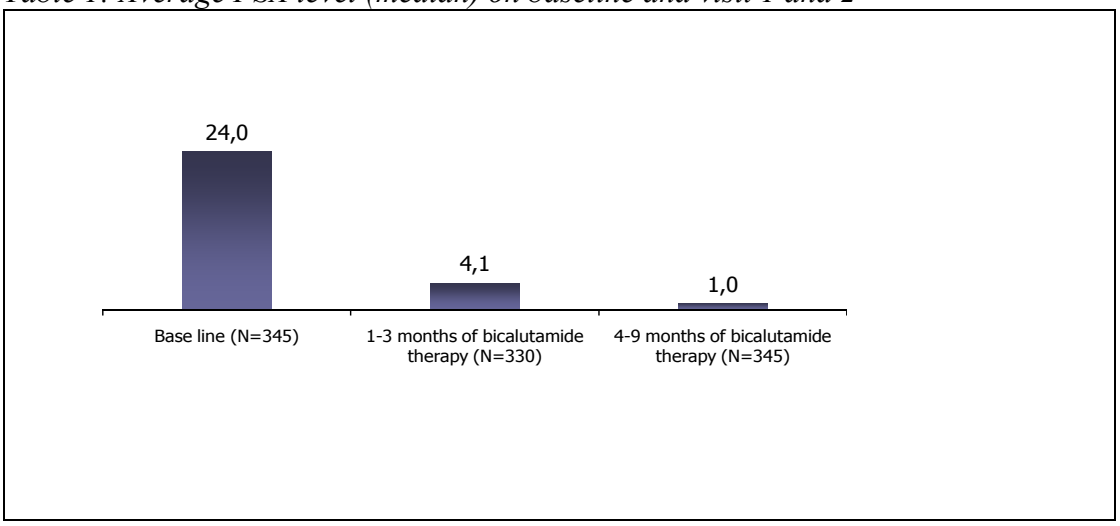
Statistical analysis
Descriptive statistical methods were used for data analysis.

RESULTS:

Demographics
In total, 340 patients were enrolled in the study. Most patients were between 61 and 80 years old with minor proportions of patients younger than 60 and older than 80 years.

PSA level
One of the primary outcome variables was follow up of PSA level after 7-9 months of bicalutamide therapy.
Level decreased from baseline (at the moment when bicalutamid introduced in therapy) to the Visit 2 – 7-9 months of bicalutamide therapy (see table 1).

Table 1: Average PSA level (median) on baseline and visit 1 and 2



These results showed significant changes in PSA level during the study.

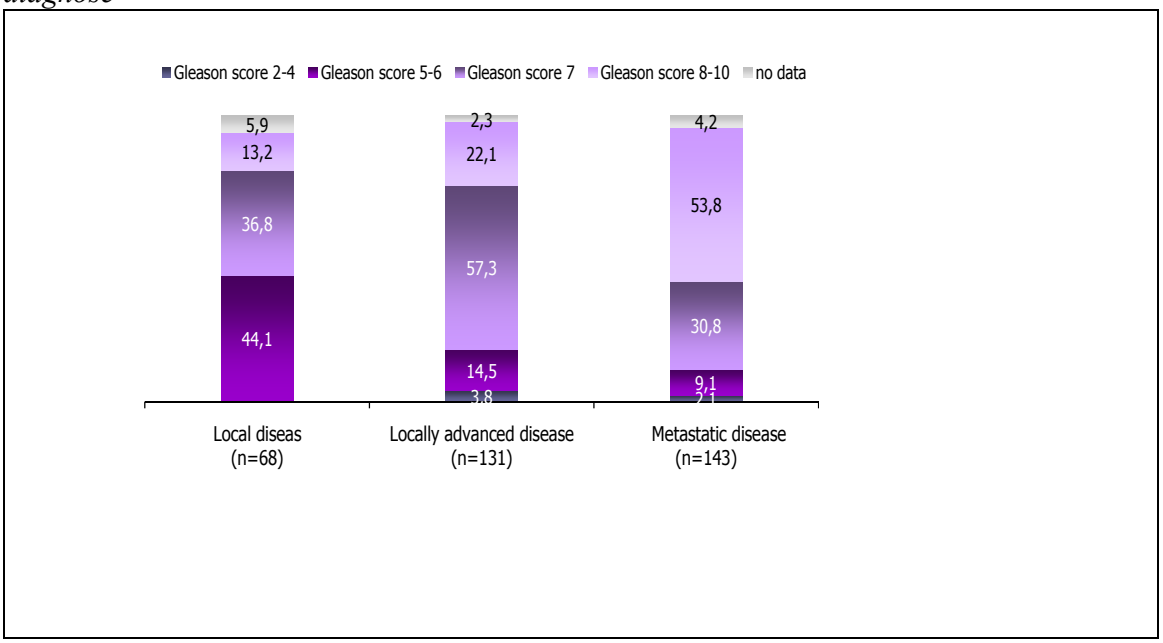
Medical History

Locally advanced or metastatic prostate cancer was recorded in 79% of patients. In those patients with metastatic disease 35,4% of patients have bone metastases, 7,5% of patients metastases have in lymph nodules, 0,9% in visceral organs. For 56,2% of patients were not specified where metastases are.

Previous therapy was recorded in 10,1% of patients. In those patients, most frequent therapy were: surgical castration in 69,2% of patients; LHR therapy in 10,1% of patients (Zoladex in 91,7% of patients) and antiandrogen hormonal therapy in 52,7% of patients (Androcur in 30,6%, Casodex in 24,6% and Flutamid in 16,4% of patients). Each tenth patient (11,1%) was under went radical prostatectomy and postoperative radiotherapy (10,1%). No patient with history of chemotherapy.

In patients with metastatic disease the most frequent GLEASON score were between 8 and 10. The most frequent GLEASON score in patients with locally advanced disease were 7 (see table 3).

Table 3: Frequency of GLEASON scores related to present status of disease at the moment of diagnose



Evaluation of disease

Evaluation of disease according PSA level and clinical status, during this study, at visit 1 improvement was recorded in 71,2% of patients, stable disease in 21% of patients and disease progression disease in 2,6% of patients related to baseline. At visit 2 improvement was recorded in 80,4% of patients, stable disease in 13% of patients and disease progression in 5,5% of patients related to baseline.

Further therapy with bicalutamide

At the visit 1, 7 patients (2%) did not continue bicalutamide therapy - 1 patient because of disease progression and 5 patients because of disease improvement. One patient was turned out by Croatian Institute for Health Insurance.

At the visit 2 majority of patients (92,2%) continued bicalutamide therapy. Therapy was stop in 21 cases. 10 patients were turn out because of disease progression, 6 because of improvement and 5 because of Croatian Institute for Health Insurance.

Adverse event

No adverse events were reported in this study.