

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT:

N/A

ACTIVE INGREDIENT:

N/A

Study No: NIS-OCZ-FAS-2010/1

Reasons for Changing HOrmonal Therapy of Advanced Breast Cancer (HOT ABC)
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Developmental Phase: non-interventional study

Study Completion Date: 20th November 2011

Date of Report: 9th December 2011

RATIONALE FOR THIS NON-INTERVENTIONAL STUDY

Breast cancer is the leading type of cancer in women. Although big advance in diagnostics and treatment of early and breast cancer has been made in recent years breast cancer still has a significant mortality rate.

A number of treatment modalities exist for postmenopausal women with advanced breast cancer. The treatment modality is chosen based on patient and tumour characteristics. Hormonal treatment is preferred and recommended in women with hormone sensitive breast cancer (ESMO, CECOG and NCCN guidelines).

Tumor markers are an established method of monitoring systemic therapies in various cancers. Tumor markers CA 15-3 and CEA are used in clinical practice to monitor treatment efficacy of metastatic breast cancer. Blood levels of tumor markers are widely used to assess response/progression to treatment and guide therapy change. Treatment efficacy is assessed by imaging methods in clinical studies. Change of therapy in clinical study is usually done when progression based on RECIST criteria is found.

Hormonal treatment has slower onset of effect compared with chemotherapy that can last several weeks. Also when a new therapy is started spurious early rises may occur. Therefore rising levels of tumor markers during the first weeks of new hormonal therapy are not necessarily sign of progression and should not be the only guidance for treatment change. Evidence of treatment efficacy form clinical studies and treatment change is based on imaging techniques.

OBJECTIVES:

Primary objective

To describe reasons for treatment change in postmenopausal women with hormone sensitive advanced breast cancer in the Czech Republic.

Main secondary objectives

To compare and correlate tumor markers as a marker of response/progression with response/progression described by imaging techniques in postmenopausal women with hormone sensitive advanced breast cancer treated by hormonal treatment.

To assess time to progression in particular lines of therapy in postmenopausal women with hormone sensitive advanced breast cancer in real world practice.

To analyze and describe hormonal treatment in postmenopausal women with hormone sensitive advanced breast cancer in the Czech Republic.

METHODS:

This study is a retrospective epidemiological study looking into patients' medical records kept by a hospital/institution/physician. There are no scheduled visits for any patient participating in the study.

Patient population selection criteria

Postmenopausal women with hormone sensitive advanced breast cancer that have been treated with minimum two hormonal agents according to approved SmPC.

Retrospective data for eligible patients will be reviewed by participating investigators, physicians taking care of their patients, and recorded in the electronic CRF.

RESULTS:

The study has described describe reasons for treatment change in postmenopausal women with hormone sensitive advanced breast cancer in the Czech Republic.

Progression described by imaging methods was the main reason for treatment discontinuation in 63.9 % of patients treated by hormonal treatment. In 14.3 % of hormonally treated patients the reason for treatment cessation was progression assessed by the change in tumour marker levels, 9 % of patients had not tolerated their current treatment, 3.8% of patient has symptomatic progression and 9 % of patients stopped their treatment due to other reasons.

Progression described by imaging methods was the main reason for treatment discontinuation in 12.7 % of patients treated by chemotherapy. In 1.6 % of chemotherapy treated patients the reason for treatment change was progression assessed by the change in tumour marker levels, 20.6 % of patients had not tolerated their chemotherapy treatment, 3.8% of patient has symptomatic progression and 61.9 % of patients stopped their chemotherapy treatment due to other reasons. The main other reasons were: treatment response, planned number of cycles reached, surgical procedure. Maintenance treatment was started in 3.2 % of patients.