AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: None
ACTIVE INGREDIENT: None

Study No: NIS-OBR-DUM-2010/1
PATTERNS OF CARE IN HORMONE-RECEPTOR POSITIVE, ADVANCED BREAST CANCER IN BRAZIL: A PROSPECTIVE, OBSERVATIONAL STUDY

Developmental Phase: NIS
Study Completion Date: 31-Jan-2012
Date of Report: 31-Jan-2012

OBJECTIVES:

To characterize the current patterns of care for patients with hormone-receptor-positive, advanced breast cancer who have failed one prior endocrine therapy in Brazil. To investigate patient-related, disease-related and physician-related characteristics that correlate with the use of either endocrine treatment or chemotherapy in such patients. And to evaluate patients' understanding of the treatment options and their participation in the choice.

METHODS:

Prospective, observational study.

Target subject population

Postmenopausal women with advanced breast cancer, at least one positive hormone receptor, who have failed one previous endocrine therapy in the adjuvant or metastatic settings.

Investigational product, dosage and mode of administration

This is an observational study of the use of chemotherapy or endocrine therapy in patients with advanced breast cancer.

Comparator, dosage and mode of administration

Given the observational nature of this study, doses and treatment regimens will not be influenced by the protocol and will be left to the discretion of investigators and local standards of care.

Duration of treatment

Not applicable.

Outcome variables

Efficacy

Primary outcome variable:

To assess the treatment choice by the medical oncologist for each patient.

Secondary outcome variables:

- To assess determinants of treatment choice.
- To assess the duration of treatment with chemotherapy or endocrine therapy.
- To evaluate the rate of treatment continuation at 6 months.
- To assess the profile of adverse events with each treatment modality.
- To assess patient participation and understanding in treatment choice.

Safety

- To assess the most commonly reported adverse events with chemotherapy or endocrine therapy.
- To estimate the incidence of serious adverse events with chemotherapy or endocrine therapy.

Statistical methods

Despite the absence of a specific scientific hypothesis based on efficacy or toxicity endpoints, a sample size of 111 patients was calculated for the study that will give it 90% power, considering a two-sided type I error of 5%, to verify the null hypothesis that endocrine therapy is indicated as the first treatment of choice for 65% of the patients, against an alternative hypothesis that only 50% of patients with ER-positive breast cancer and failure of only one prior endocrine therapy in the adjuvant or metastatic setting receive endocrine therapy as the first treatment of choice. Assuming that there loss of data or follow-up for 10% of patients, a total of 124 patients shall be included in the study.

RESULTS:

The study presented difficulties in identifying the target population. It started on the February 8th, 2011 and until Dec 31st, 2011 only 7 subjects were included, which was far below expectations.

After discussion with the medical community in regards to design of the protocol versus inclusion expectations, it was concluded that the subject's target population is rarely found in the involved research sites, which makes continuing research impossible. Thus, AstraZeneca has decided to terminate the study due to the difficulty of identifying this population. As only 5% of subjects were included, it was not possible to have any data analysis and therefore no results are expected for this study.

With regard to the discontinuation of the Subjects, once it is a prospective, non-interventional study, there will not be any loss affecting subjects' treatment and care that he/she is entitled to receive.