STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Symbicort®
ACTIVE INGREDIENT: budesonide/formoterol

Study No: INVOLVE study, study code S43
An observational study to investigate how patients experience the ability to adjust their asthma maintenance medication according to instructions received from their physician. (INVOLVE-study)

Developmental phase: Non interventional study (phase IV)

Study Completion Date: Database lock August 2007

Date of Report: November 2008

OBJECTIVES:

The primary aim is to get insight in the perception of the patient when he has the ability to adjust his own asthma maintenance treatment (Budesonide/Formoterol Turbuhaler 200/6 Adjustable Maintenance Dosing, Bud/For 200/6 AMD) and how the patient uses it in daily practice

The secondary goal is to investigate the efficacy of the treatment with Bud/For 200/6 AMD on the patients asthma control measured with the Asthma Control Questionnaire (ACQ).

METHODS:

The study was an observational study without intervention in the treatment strategy of the patient. Patients eligible for the study were patients with asthma (18 years and older) of which the physician already had decided before the patient's participation in the study to prescribe Bud/For 200/6 AMD (at baseline or earlier).
At baseline, instructions how to use the medication, visit date, patient characteristics and general asthma control were obtained by the physician and Bud/For 200/6 AMD treatment was started or continued. At baseline and approximately 3 months after the first visit to the physician the patient filled in a questionnaire, questionnaire I (baseline) and II (3 months) respectively. The questionnaires contained questions regarding involvement and expectations of the treatment, medication instructions and use in daily practice, treatment satisfaction, reasons to adjust the maintenance dose (only in Questinnaire II) and ACQ score. Futhermore adverse events leading to discontinuation of medication (DAE) and serious adverse events (SAE) were registered. All measures were summarized by descriptive statistics.

RESULTS:

Between February 2005 and August 2007, 183 GPs participated in the INVOLVE study of which 113 GPs recruited 563 patients. In total 546 GP baseline questionnaires, 505 patient questionnaire I and 460 patient questionnaire II were obtained. From 424 patients all questionnaires (both physician and patient questionnaire I and II) were obtained.

Baseline data

Baseline data of the patients showed that 36% of the included patients were male, 34% had mild asthma, 56% moderate asthma and 9% severe asthma and 10% already used Bud/for 200/6 AMD before participation in this study.

The involvement and expectations of patients and physicians in the treatment with Bud/For 200/6 AMD

61% of the physicians expected at baseline that patients appreciate the use of AMD in daily practice whereas 73% of the patients at baseline and 83% after 3 months of AMD treatment appreciated it.

72% of the physicians thought at baseline that using AMD will give better asthma control. The patients were more careful, 51% expected at baseline a better asthma control and 59% after 3 months of AMD treatment.

The instructions of the physician regarding Bud/For 200/6 AMD and use in daily practice

In 99% of the cases physicians gave instructions regarding maintenance dosage and in 97% of the cases also the maximum dosage was mentioned. In 94% of the cases the physician also gave instructions when to increase/decrease the maintenance dosage and when to contact the physician. In 91% of the cases the pharmacist was informed.

In daily practice 60% of the patients did not use extra inhalations. If extra inhalations were taken 79% of the patients took 1-2 extra inhalations. Mean duration of extra inhalations was 2-5 days.

Treatment satisfaction of the patients with Bud/For 200/6 AMD

56% of the patients at baseline and 68% of the patients after 3 months of AMD treatment were satisfied with the fast onset of action regarding symptom reduction.

After 3 months of AMD treatment 78% of the patients were overall satisfied with the treatment.

Reasons to adjust the maintenance dosage

The most occuring reasons for the patients to adjust the maintenance dosage were:

- More daily symptoms than normal
- Flu or cold
- Wheather changes

ACQ score

The ACQ score decreased from 1,9 at baseline till 1,2 at 3 months of Bud/For 200/6 AMD treatment.

The ACQ score decreased overall; also in patients of whom the physician initially, at baseline, had expected that the ACQ would not change in time due to Bud/For 200/6 AMD treatment.