AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Symbicort Turbuhaler
ACTIVE INGREDIENT: Budesonide / Formoterol

Study No: NIS-RRO-SYM_2008/1
SMART way of treating asthma.
Non-interventional study to evaluate clinical efficacy of Symbicort® Maintenance And Reliever Therapy (Symbicort® SMART) in the treatment of patients with moderate and severe asthma

Developmental Phase: post marketing, non-interventional observational study Study Completion Date: 15.12.2009

Date of Report: 15.10.2010

OBJECTIVES:

The primary objective of this non-interventional study was to evaluate efficacy of Symbicort® SMART treatment in adult patients with moderate to severe asthma using ACQ scores recorded during 5 visits: visit 2 (week 4), visit 3 (week 8), visit 4 (week 12 or 16) and visit 5 (week 16 or 24) compared with scores recorded in visit 1 (week 0).

METHODS:

This prospective, non-interventional study included 1184 patients with moderate and severe asthma. The patients were having documented history of moderate and severe asthma and were on treatment with Symbicort® SMART for at least 1 month prior to inclusion.
There were scheduled four points of collection of data, patient visits done in accordance to current clinical practice, during 6 months period.
Asthma Control Questionnaire© was self administrated by patients on all visits and results included in the CRF.
A written consent for data review and processing was obtained from each patient.

Inclusion Criteria:

- Patients eligible for entry into study are the patients diagnosed with moderate to severe asthma, that the doctors have already decided to treat with Symbicort® SMART within the last month, before inclusion in this program, according to Romanian approved SmPC (attached to the protocol).
- Patients, male or female, age 18 or older with diagnosed moderate to severe asthma
- Have already been on Symbicort® SMART treatment since at least 1 month
- Willing to give written informed consents to obtain the agreement to use personal data

Exclusion Criteria:

- Patients who have a known hypersensitivity to budesonide, formoterol or any of Symbicort® excipients.

Statistical methods:
Simple descriptive statistical analysis included record of sex, age and ACQ of each visit according to study design. The results are presented as value ± standard deviation (SD).

RESULTS:

Subject population:

Characteristic		Statistic n (%)
Sex	Male	726 (61.31)
	Female	458 (38.68)
Age (years)	Mean	48.36
	SD	15.17
	Median	50
	Minimum	18
	Maximum	88
Asthma severity	Mild persistent	907 (76.6)
	Severe persistent	277 (23.4)
ACQ $_5$ at Visit 1 (week 0)	Mean	2.44
	SD	1.31
	Median	2.4
	Minimum	0.00
	Maximum	6

The doses used at the enrollment (week 0) were:

- Symbicort® Turbuhaler 80/4.5 µg – 20 patients (1.6%)
  - 2 x 1 dose/day + as needed – 10 patients (0.8%)
  - 2 x 2 dose/day + as needed – 10 patients (0.8%)

- Symbicort® Turbuhaler 160/4.5 µg – 1164 patients (98.3%)
  - 2 x 1 dose/day + as needed – 841 patients (71.0%)
  - 2 x 2 dose/day + as needed – 323 patients (27.3%)

Efficacy results (ACQ_5):
During the study all patients were monitored for 16 weeks with a mean period of 126.75 days ± 21.2. A number of 779 (65.79%) patients performed a supplementary visit at week 24 (amendment 1); for these patients the mean duration of follow up was 176.25 ±15.26 days.

Mean values from following visits (2-5) measured for ACQ_5 recorded was:

- Visit 2 (week 4): 1.69 ±1.11
- Visit 3 (week 8): 1.30 ±1.0
- Visit 4 (week 16): 0.96 ±0.9

For the patients additionally monitored at week 24, the mean value of ACQ $_5$ recorded was 0.78 ± 0.84.

The mean variation of ACQ_5 score calculated between end point (week 16) and baseline (week 0) was -1.48 (95% CI; 1.35; 1.6) $p<0.001$ decrease of score and -1.68 (95% CI; 1.52; 1.85) $p< 0.0001$ for subgroups which included the additional visit.

Safety results:

The safety data collected do not raise new concern related to the treatment with budesonide / formoterol combination.
AE reported during the study included headache, vertigo, rhino-pharigitis and palpitation.
No withdrawal due to AE was registered.
No deaths reported.
40 SAE, due to hospitalisation for primary condition, asthma, occurred during the study.
A number of 6 patients were lost of follow up.