AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: SYMBICORT® TURBUHALER®
ACTIVE INGREDIENT: budesonide/formoterol

Study No: NIS-RSI-SYM-2006/1, NCT00837629
Evaluation of Symbicort® Turbuhaler® (budesonide/formoterol) in chronic obstructive pulmonary disease (COPD)

Developmental phase: Post-marketing non-interventional study
Study Completion Date: September 2007
Date of Report: September 2008

OBJECTIVES:

PRIMARY OBJECTIVE

Analysis of the overall status improvement with Symbicort Turbuhaler in the enrolled patients, assessed by reduction in overall Clinical COPD Questionnaire (CCQ) score between the initial and follow-up visit after 12 weeks or differently at physician's discretion.

SECONDARY OBJECTIVES

- Physicians' global clinical impression of the treatment.
- Evaluation of smoking habits among the enrolled patients.

METHODS:

This trial was a prospective, non-randomised, non-interventional follow-up clinical study. The study analysed the therapeutic effectiveness in patients with severe COPD following a generally accepted 12-week treatment period with Symbicort Turbuhaler, which could anyhow be shortened or extended at physician's discretion. Symbicort Turbuhaler was administrated upon the recommendation of the treating physician. Any additional therapy (initiation, adjustment, discontinuation) for COPD and/or concomitant diseases/conditions was decided upon by the treating physician according to the patient's clinical status and the current professional guidelines. All additional COPD therapy was duly documented in the questionnaires.

The study included 742 patients with severe COPD. One hundred and twelve (112) physicians with a specialty in family medicine or pulmology participated as investigators in the study. The study focused on assessment and evaluation of the burden of COPD using the Clinical COPD Questionnaire (CCQ) – a validated questionnaire assessing the most important items of the COPD specific clinical health status: symptoms, functional state and mental state.

RESULTS:

PRIMARY OBJECTIVE

Reduction in overall CCQ score

Reduction in overall Clinical COPD Questionnaire (CCQ) score between the initial and follow up visit was 1.2 units, which is three times more than the value which was defined as clinically important (reduction in CCQ score of et least 0.4). The difference reached a statistical significance ($P < 0.0001$; 99% CI, 1.1).

SECONDARY OBJECTIVES

Physicians' global clinical impression of the treatment

Physicians' global clinical impression was summarised using descriptive statistics of the five possible marks (excellent, very good, good, acceptable, poor) at the end of the trial (Table 1).

Table 1: Physicians' global clinical impression of the treatment

Mark	**N**	**%**
Excellent	201	27.1
Very good	301	40.6
Good	187	25.2
Acceptable	33	4.5
Poor	4	0.5
No data	16	2.1
Total	742	100

Adverse events

No adverse events were recoded in 724 (97.6%) patients. For 14 (1.9 %) patients there was no data about adverse events. In 4 (0.5%) patients the following adverse events were recorded: bruises of the skin, cramps in legs, faster heart beat, pain in wrists, troubles with a tongue, hoarseness.

Evaluation of smoking habits

Data about smoking habits of patients as recorded at the initial visit is shown in Table 2.

Table 2: Smoking habits of patients

	Males N (%)	**Females N (%)**	**No data about gender**	**Total N (%)**
Current smokers	167 (32.6)	67 (29.5)	2	236 (31.8)
Non-smokers	299 (58.4)	98 (43.2)	1	398 (53.6)
Ex-smokers	46 (9.0)	62 (27.3)	0	108 (14.6)
Total	512 (100)	227 (100)	3	742 (100)

Of 236 smokers, 92 (39%) patients changed their smoking habits during the study as recorded at the follow-up visit. Of those 92 patients, 29 patients gave up smoking and 62 patients reduced it, for 1 patient there is no data. No patient started smoking during the study.