**INTRODUCTION**

Dry powder inhalers (DPIs) containing the corticosteroid budesonide and the rapid- and long-acting β2-agonist formoterol are used for maintenance treatment of patients with moderate-to-severe asthma or chronic obstructive pulmonary disease (COPD). The combination has also been approved for as-needed treatment in addition to regular maintenance therapy because of the rapid onset of dose-dependent bronchodilation with formoterol.

Easyhaler is a multi-dose DPI designed to be simple and easy for asthmatic and COPD patients to use. Budesonide/formoterol combination treatment was evaluated in a single dose double-blind study comparing efficacy of Easyhaler and Turbuhaler in stable but less than optimally controlled patients with asthma.

**AIMS**

The study aimed to confirm equivalent bronchodilator efficacy of budesonide/formoterol combination delivered via Easyhaler and Turbuhaler in asthmatic patients.

**METHODS**

**Study population**

- **Patient selection**: Patients aged 18-70 years with a history of moderate-to-severe asthma diagnosed according to Global Initiative for Asthma (GINA) 2014 for at least 6 months, a forced expiratory volume in one second (FEV1) between 50% and 80% of the predicted value (GLI-2012 reference values) and a post-bronchodilator FEV1/FVC ratio of at least 0.7, with well-controlled eosinophil counts.

**Endpoints**

- **Primary efficacy endpoint**: The average 12-h FEV1 after inhalation of the study treatment was not to differ more than 12% compared to the screening value.
- **Secondary efficacy endpoints**: Concentration of the corticosteroid budesonide and the rapid- and long-acting β2-agonist formoterol in the respiratory tract 2, 3, 4, 6, 8, 10 and 12 h after administration of the study treatment were calculated on the basis of area under curve (AUC) of FEV1.

**Statistical analyses**

The results of the primary efficacy endpoint were evaluated in a direct comparison between Easyhaler and Turbuhaler. An analysis of covariance model was used to compare the maximum response and the duration of effect after both products.

**RESULTS**

- **Efficacy**: The maximum response and the duration of effect are similar after both products.
- **Safety**: There were no discontinuations due to AEs during the study. 6 patients reported a total of 9 AEs during the study. The AEs were equally distributed with no unusual findings in physical examination, vital signs, ECG or laboratory parameters at the end of study compared to screening.

**CONCLUSIONS**

The study was designed and sponsored by Orion Pharma.

**REFERENCES**