20 February 2014
EMA/CHMP/89644/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Laventair

umeclidinium bromide/vilanterol

On 20 February 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Laventair, umeclidinium bromide 55 µg / vilanterol 22 µg, inhalation powder, pre-dispensed, intended for the symptomatic treatment of chronic obstructive pulmonary disease (COPD). The applicant for this medicinal product is Glaxo Group Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

Laventair (ATC code: R03AL03, Drugs for obstructive airway diseases, adrenergics in combination with anticholinergics) is a fixed-dose combination of the active substance umeclidinium bromide, a long acting muscarinic receptor antagonist (also referred to as an anticholinergic), and the active substance vilanterol, a selective long-acting beta$_2$-adrenergic receptor agonist. Long acting muscarinic receptor antagonists exert their bronchodilatory activity by competitively inhibiting the binding of acetylcholine with muscarinic acetylcholine receptors on airway smooth muscle. Beta$_2$-adrenergic receptor agonists stimulate intracellular adenylate cyclase which converts ATP into cyclic AMP. Increased cyclic AMP levels cause relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.

The benefits with Laventair in the treatment of COPD are its ability to improve the trough FEV1 (lung function endpoint) and to improve the TDI focal score (symptomatic endpoint) at week 24 in 6 months studies versus placebo.

The most common side effects are nasopharyngitis and headache. An increased incidence of cardiovascular and cerebrovascular events that may occur with long-term use of Laventair is a potential safety concern. However robust long-term (> 1year) safety data is not yet available. Therefore cardiovascular and cerebrovascular events have been included as an important potential risk in the Risk Management plan and the applicant will conduct a post-authorisation safety study to further investigate this risk.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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A Pharmacovigilance plan for Laventair will be implemented as part of the marketing authorisation.

The approved indication is:

Laventair is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Laventair and therefore recommends the granting of the marketing authorisation.