26 January 2017
EMA/CHMP/39488/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rolufta

Umeclidinium bromide

On 26 January 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rolufta, intended for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).The applicant for this medicinal product is GlaxoSmithKline Trading Services Limited.

Rolufta will be available as an inhalation powder (55 microgram). The active substance of Rolufta is umeclidinium bromide, a long-acting muscarinic receptor antagonist that exerts bronchodilatory activity by competitively inhibiting the binding of acetylcholine to muscarinic cholinergic receptors on airway smooth muscle cells (ATC code: R03BB07).

The benefits with Rolufta are its ability to improve the trough FEV_1 (lung function endpoint) and COPD symptoms as measured by TDI SGRQ score responders. The most common side effects are nasopharyngitis and upper respiratory tract infection. Cardiovascular and cerebrovascular events with Rolufta are a potential safety concern. 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.

The application for Rolufta was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Rolufta is Incruse.

The full indication is:

> "Rolufta 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.

[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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