EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2019
EMA/CHMP/228757/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Temybric Ellipta

fluticasone furoate / umeclidinium / vilanterol

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Temybric Ellipta, intended for the maintenance treatment of adults patients with moderate to severe chronic obstructive pulmonary disease. The applicant for this medicinal product is GlaxoSmithKline Trading Services.

Temybric Ellipta is a combination of fluticasone furoate, umeclidinium and vilanterol (ATC code: R03AL08). It will be available as inhalation powder (92 micrograms / 55 micrograms / 22 micrograms). Both umeclidinium (a long-acting muscarinic receptor antagonist) and vilanterol (a selective long-acting, $beta_2$-adrenergic receptor agonist) act locally to relax bronchial smooth muscle by separate mechanisms, whereas fluticasone furoate is a corticosteroid which reduces inflammation.

The benefits with Temybric Ellipta are its ability to improve lung function (as defined by change from baseline trough FEV_1 at Week 24). The most common side effects are nasopharyngitis (7%), upper respiratory tract infection (2%) and headache (5%).

The full indication is:

Temybric Ellipta is indicated as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting β2-agonist or a combination of a long-acting β2-agonist and a long-acting muscarinic antagonist (for effects on symptom control and prevention of exacerbations see section 5.1).

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union