

GSK, Theravance COPD drug gets FDA nod

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Singapore: The US FDA's Pulmonary-Allergy Drugs Advisory Committee (PADAC) has approved GlaxoSmithKline (GSK) and Theravance's Breo Ellipta as a once-daily inhaled treatment for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD)) and also for the reduction of COPD exacerbations in patients with a history of exacerbations.

Breo Ellipta, is the proposed proprietary name for FF/VI 100/25 mcg, a combination of the inhaled corticosteroid (ICS) fluticasone furoate (FF) and the long acting bronchodilator (LABA) vilanterol VI (FF/VI). The FDA advisory committee also voted that the safety of FF/VI 100/25 mcg once daily in COPD has been adequately demonstrated for the proposed indications (10 for, 3 against).

Dr Patrick Vallance, president, pharmaceuticals R&D, GSK, said that, "We are pleased with the outcome. COPD is a debilitating and progressive disease. Its symptoms are often severe and can have a huge impact on patients' lives. This positive recommendation is a crucial first step towards making Breo Ellipta available for appropriate COPD patients across the US. We look forward to a final decision from the FDA later this year."

"After a decade of development in this programme, our collaboration with GSK is one step closer to providing an important therapeutic option to COPD patients," said Mr Rick E Winningham, CEO, Theravance. "We are proud to collaborate with GSK on the development and potential commercialisation of treatments for COPD and other respiratory diseases. The panel's positive recommendation of Breo Ellipta represents an important achievement in a transformative year for Theravance."

In July 2012, a new drug application (NDA) was submitted to the FDA for the use of Breo administered by the Ellipta inhaler for the long-term once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema, and to reduce exacerbations of COPD in patients with a history of exacerbations.