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GSK, Theravance seek EU nod for COPD drug

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Singapore: GlaxoSmithKline (GSK) and Theravance submitted a regulatory application in the European Union for the investigational once-daily LAMA/LABA combination medicine, UMEC/VI, for patients with chronic obstructive pulmonary disease (COPD).

UMEC/VI is a combination of two investigational bronchodilator molecules, including GSK573719 or umeclidinium bromide (UMEC), which is a long-acting muscarinic antagonist (LAMA); and vilanterol (VI), a long-acting beta2 agonist (LABA), administered using the Ellipta inhaler.

A Marketing Authorisation Application (MAA) for UMEC/VI (55/22mcg and 113/22mcg doses), with the proposed proprietary name Anoro, has been submitted to the European Medicines Agency (EMA) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

The UMEC/VI doses of 55/22mcg and 113/22mcg are specified as the delivered doses (emitted from the inhaler) which are equivalent to the 62.5/25mcg and 125/25mcg pre-dispensed doses (contained inside the inhaler) submitted for approval in the US.

Regulatory submissions for UMEC/VI are planned in other countries during the course of 2013. In addition, GSK intends to commence global regulatory submissions for UMEC monotherapy later this year.