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GSK, Theravance withdraw COPD drug from Japan

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Singapore: GlaxoSmithKline and Theravance have withdrawn license application for the use of inhaled drug fluticasone furoate (FF) and vilanterol (VI), with proposed brand name of Relvar Ellipta, as treatment for chronic obstructive pulmonary disease (COPD) in Japan.

The companies have decided to pull the application as no Japanese patients were included in two longer 52-week exacerbation studies of FF/VI and the six-month clinical data on the drug might not be strong enough to secure approval. Data from six studies, which included over 6,000 COPD patients, was included in the Japanese filing.

Two six-month efficacy studies that demonstrated the benefit of the combination FF/VI against placebo on the co-primary endpoints of zero-to-four hour weighted mean FEV1 and trough FEV1 generated Japanese patient specific efficacy data.

According to the data from studies that assessed the contribution of each of the individual components, VI achieved a statistically significant improvement in weighted mean FEV1 and FF did not achieve statistical significance on improvement of lung function.

As part of the Japanese New Drug Application (JNDA), the review of FF/VI for asthma remains under review through the normal Japanese regulatory process.