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GSK - FDA Advisory committee positive on Anoro Ellipta - First once daily dual bronchodilator for US COPD patients

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Abstracts

GSK and Theravance jointly announced that the FDA pulmonary allergy Drugs Advisory Committee recommended in favor of approval (11-2) for the once daily, lower dose regimen (Vilanterol-62.5 mcg/ Umeclidinium 25 mcg). The committee unanimously voted in favor of efficacy, while safety votes were divided (10-3). The higher dose (125/25 mcg) of Anoro was not considered by USFDA for voting. The PDUFA date of Anoro is Dec 18, 2013 and a timely approval will make Anoro the first dual bronchodilator to be launched in the US. We expect Anoro to garner global peak sales of $ 1.5b. Anoro once launched will cannibalize the market of twice daily LABA's (formoterol and Salmeterol) and Spiriva. LABA's are primarily co-prescribed as second line treatment agents in COPD patients and about 25-30% of Spiriva prescriptions have LABA's as coprescribed drugs. We see the market for Spiriva getting impacted to that extent. The MAA (Europe) for Anoro has already been filed in Europe and expected to receive approval by the end of this year. The submission of the regulatory application to the Japanese ministry has been done in Apr 2013.

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