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GlaxoSmithKline - Relovair - Crosses the safety hurdle, while needs more data on the efficacy front

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Abstracts

GSK and Theravance jointly announced their completion of pivotal studies of once daily Relovair and their intention to file Relovair globally for COPD (100/25 mcg dose) and in Europe for Asthma indications by mid-2012. The announced data shows that on efficacy, Relovair is better than its individual components and comparable to Seretide/Advair (24 hr mean FEV1) while there are no safety concerns. We believe the non-pivotal study comparing Relovair to Advair in Asthma (n=500 patients, 24 weeks) was relatively smaller and shorter for the clinical implications of the compliance benefit to be reflected in patient benefit/outcome. Based on GSK’s confidence on regulatory filing, it seems there are unlikely to be any safety concerns (except fatal pneumonia reported with higher dose regimen-200/25 mcg). Company is planning to conduct OUTCOME study with 16000 patients to prospectively evaluate the effect of Relovair compared with placebo on survival in COPD patients with a history of or at risk from CV disease.

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