

Actos Bladder Cancer Concerns -Anti-diabetic Class Bracing For Newer Therapies

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Abstracts

The European Medicine Agency (EMA) or/and the USFDA may or may not chose to follow the French or German regulators that have suspended partial to full use of Actos, but with the news already in the market, Actos is expected to lose market share. At a minimum, assuming no further regulatory action, Actos may sill loose 30% sales. Besides this, we see wide ranging implications on the entire diabetes class.

Our discussion with key opinion leaders (KOLs) suggests that the recently issued warning by the USFDA (increased risk of bladder cancer on long term use of actos) would lead to restricted use of Actos. The use of Actos will be restricted to a couple of months or to the low dose regimen. The use of Actos would primarily be aimed at removing hepatic fat accumulation in patients, and thus help reduce insulin resistance. Based on our discussion with KOLs, the major beneficiaries out of Actos loss would be primarily the GLP-1's (Table-1) and to some extent the DPP-IV's and insulin. Dapagliflozin, which is expecting approval by YE 2011, may also find the time ripe for a successful launch, as doctors may need an additional oral treatment option to replace pioglitazone, in case of patients who are not willing to switch to an Injectable.

Actos patent is expiring next year and hence the decline in prescriptions would not be much of a concern for Takeda. Actos sales in EU is just ~¥30b and hence in the event EMA opts for withdrawal, the EPS impact will be negligible. But if this extends to the US (expected to decide in next couple of months), it may translate into ~¥1.7b revenue loss (EPS impact ~¥100/share or

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COMPANIES MENTIONED

USV, SUN PHARMA, Abbott, Takeda, LLY, BMY

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