Evaluate Vantage

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Event – Alogliptin PDUFA crucial to Takeda

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Faced with losing patent protection in 2011 for Actos, the world's biggest-selling anti-diabetic drug, and its second-most valuable product Takeda, the Japanese pharma giant, will be crossing all its fingers and toes that the FDA approves its biggest pipeline drug alogliptin (SYR-322). A regulatory decision is expected by the end of October.

Representing a new class of anti-diabetic agent, alogliptin should be the second dipeptidyl peptidase IV (DPP-IV) inhibitor onto the US market, behind Merck & Co's phenomenally successful Januvia. Takeda will be hoping alogliptin follows Januvia's best-in-class example and avoids the safety issues which hit Novartis' Galvus, which should have been the second DPP-IV inhibitor to market.

Increasing confidence

Alogliptin is easily Takeda's most valuable pipeline drug with forecast sales of $2bn in 2014, valued at $3.79bn or 10% of the company's share price, according to EvaluatePharma's NPV Analyzer.

Takeda's reliance on the successful commercialisation of alogliptin has assumed even greater importance following the high-profile failure of TAK-475, a potential cholesterol-lowering blockbuster drug (*Takeda says goodbye to TAK-475, March 28, 2008*).

Analyst confidence that alogliptin's side effect profile should not raise alarm bells at the increasingly cautious FDA is reflected in a 26% increase in consensus forecasts over the last 12 months for sales in 2012, rising from $1.07bn to $1.34bn.

However, doubts remain as to the drug's efficacy when directly compared to Januvia (*ADA - DPP-IVs and GLP-1s steal the show, June 9, 2008*). As a result, FDA approval may just be the first hurdle the drug needs to clear, before the real challenge of grabbing market share from Januvia begins.

Bargain deal

Takeda acquired the rights to alogliptin through its $270m takeover of Syrrx in 2005, when the drug was still in phase II trials. Although phase III diabetic clinical trials for the drug would have been fairly costly, with a current NPV of $3.79bn, this deal looks like a pretty shrewd piece of business, assuming major regulatory hurdles are successfully cleared.

In contrast, a significant return on the $8.8bn Takeda forked out to acquire Millennium Pharmaceuticals this year still appears a long way off, with the sum of Millennium's products valued at just $1.86bn.

OSI the ultimate winner

Another company that has a vested interest in the regulatory and commercial success of alogliptin is OSI Pharmaceuticals. Holding the rights to a portfolio of DPP-IV patents, OSI receives royalties on sales of all DPP-IV inhibitors. (*Why OSI will always win in the DPP-IV diabetes drugs market, November 9, 2007*)

The royalty stream from DPP-IV inhibitors is valued at $1.16bn to OSI, out of a market capitalisation of $2.3bn. With alogliptin potentially worth $437m to OSI, the company is likely to be contributing to Takeda's prayers for a positive FDA verdict.