Evaluate Vantage

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Salix takes Relistor's commercial reins from Pfizer

Salix Pharmaceuticals not only believes it can succeed where the marketing might of big pharma has failed, it has put its money where its mouth is. In what could arguably be described as a brave move the company has taken over rights to constipation therapy Relistor from Pfizer, paying $60m upfront for a product that has resoundly disappointed since it was launched three years ago.

As it stands Salix's prediction that Relistor could generate $1bn annually looks wildly optimistic – the drug sold $16m last year. But the company is riding on a wave of optimism around its own lead product, diarrhoea drug Xifaxan, which is waiting to hear on a potentially lucrative new US approval in irritable bowel syndrome (IBS) – analysts are forecasting blockbuster potential. As such, Relistor could well do better at GI-focused Salix - something that the drug's owners, Progenics Pharmaceuticals, will also be hoping for.

Lack of attention

Salix believes Relistor suffered from a lack of attention at Pfizer, which inherited the drug with Wyeth. This could certainly be true but even when Wyeth was fully on board the project was beset with delays and confidence in the drug's commercial prospects had dimmed, even before Pfizer emerged on the scene (*Progenics needs the tide to turn on Relistor, October 24, 2008*).

However, Salix will certainly be more focused on wringing what it can out of the drug. A mu–opioid receptor antagonist, Relistor is indicated for opioid-induced constipation (OIC) patients that have failed on palliative care such as laxatives, and Salix sees this as an unmet need that health authorities will pay for.

And as well as the approved, subcutaneous form of the drug, the company will be taking over development of a potentially more valuable oral version.

A 700-patient oral phase III programme, initiated in September, is due to complete enrolment by the end of this year, with top line results expected mid-2012.

Expensive deal

In total the deal has cost $60m upfront, plus regulatory milestones of up to $90m, up to $200m in sales-based milestones and tiered royalties on US sales. Salix will also hand over 60% of any sublicense revenues from outside of the US, should such a deal be struck.

Considering Relistor's history and concerns that another pivotal oral trial might be required by regulators, this is not a cheap deal and UBS analysts tracking Salix described the deal as "expensive".

Still, Salix executives are confident.

"It gives us another billion dollar drug opportunity that fits nicely in our bag," Salix's chief executive Carolyn Logan said on a conference call yesterday

Value driver

Although risks remain, the oral version does represent a real value driver.

Salix also reckons the efficacy profile seen in the subcutaneous form should lower the regulatory hurdle for the new oral pill, and support a filing. The company said it had seen as-yet-unpublished phase II data on the oral pill, saying they were "very impressed."

On top of this, Relistor is also being developed for chronic non-malignant pain in OIC patients, and a supplementary filing is planned for this year.

Salix is planning to promote the drug initially to its own, familiar network of gastroenterologists. The company believes Relistor's poor launch could be rooted in the fact that just 10% of prescriptions were from gastroenterologists, a space where Salix is already actively promoting Xifaxan. Analysts expect sales of the drug to top $1bn by 2014, after reaching $250m last year.

With a broad GI-portfolio Salix appears better placed, and more motivated, to direct this programme than Pfizer. A lot still has to fall into place and the deal has not come cheap, but if sales build ahead of a successful oral project Salix could well make it work.