Evaluate Vantage

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Iluvien launch details awaited following Alimera's European win

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At least Alimera Sciences got one of the approvals it needed. After two rejections by the FDA, punctuated by a call for two more clinical trials, UK regulators last week approved Iluvien, opening the door to marketing the steroid-secreting implant for diabetic macular oedema (DME) in the EU's largest countries.

The decision breathed some life back into the Georgia group's shares - the stock has more than doubled since to $3.73, helped along by anticipation of a partnership or outright takeout. Analysts are expecting further news on the launch this week when Alimera announces 2011 year-end financial results; however, it will take a great deal more positive news to return shares to the company's 2010 float price of $11.

A win is a win

The UK's approval under the EU decentralised approval opens the door for reciprocal approvals in Germany, France, Italy, Spain, Austria and Portugal, six countries where Alimera had already filed the drug using an identical package.

Following approval from the UK Medicines and Healthcare Products Regulatory Agency, the remaining six countries have 30 days to sign their approvals.

The combined population of the seven countries is more than 300 million; citing data from the International Diabetes Federation, the company says 22.1 million people in those countries are living with diabetes. That makes it as significant a market as the US in terms of size.

However, payment policies tend to be less generous and European health systems tend to be more vigorous in making cost-effectiveness analyses, so this is not quite the commerical triumph that a US win would have meant. But given that Iluvien remains the only Alimera product close to market, progress in European is a bit of good news for a company that so far has seen little but bad.

Approval was essential for securing a partner for the region, which should lead to another share uplift as it removes uncertainty about the ability of Iluvien to launch, not to mention provide funding for further trials to win US approval, should the company still want to pursue that option. PSivida would also benefit - it is due one-third of ex-US upfront and milestone payments.

Data troubles

Diabetic macular oedema is a complication of blood vessel damage resulting from long-term uncontrolled blood glucose levels. The blood vessels of the eye can leak into the macula, causing it to swell and resulting in blurred vision.

Iluvien is a tiny tube containing 190 micrograms of fluocinolone acetonide, a steroid used to relieve skin inflammation. The tube is inserted into the eye via an injection; using technology licensed from Australian company pSivida, it then releases the steroid over 24-36 months to relieve the swelling.

The FDA initially rejected Iluvien's application using 24 month data in which one statistical measure was missed, asking to see longer-term data (*Alimera gets unwelcome Christmas message from FDA, December 24, 2010*). Even with the 36-month perspective, the data was unconvincing to regulators, triggering the call for additional trials (*Alimera and pSivida strike out, November 14, 2011*).

Euro focused?

Analysts from Credit Suisse, one of the only brokers to cover the company, have pencilled in $226.3m in non-US sales in 2015. The bank assumes Alimera will partner the drug at some point, and receive a 15% royalty on net sales.

In September 2011, before the FDA's decision, analysts were estimating sales of $417m in 2016, *EvaluatePharma*data show. Still, given that another negative decision would have completely crushed Alimera,

the possibility of any revenues in the near future can be considered a small positive.

Whether or not the revenue flow will be sufficient to pay for additional US trials remains to be seen, as does the company’s desire to throw any more money at US approval. Given the disappointment so far, finding a partner willing to pay for more US trials will be a hard ask. It would not be surprising to see Alimera make a decision to focus on growing its Iluvien business in Europe and the rest of the world.