Evaluate Vantage

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Alimera and pSivida strike out

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Two strikes may be enough to knock Iluvien out of its regulatory ball game. On Friday came news of a second complete response letter from the FDA for the eye implant drug to treat diabetic macular edema (DME), sending the shares of its developers, Alimera Sciences and pSivida, tumbling to record lows.

Fundamental to the disappointment is the FDA's request for not one but two additional clinical trials to prove Iluvien is safe and effective in DME – essentially sending the drug back to the drawing board. Alimera, shares in which were hammered 73% down to $1.96, is maintaining its commitment to the drug for now, not least because approval in Europe could still be forthcoming with the UK's MHRA due to make a recommendation by the end of the year. Whether the company attempts a third strike in the US will depend on the outcome of a review meeting next month with the FDA.

All in

Regulatory progress with Iluvien is critical to the prospects of both companies (*Event - Alimera and pSivida hope Iluvien will be second time lucky, October 10, 2011*).

Alimera developed Iluvien – a tiny injectable implant to the eye that slowly emits a very low dose of the corticosteroid fluocinolone acetonide – with technology licensed from pSivida, the Australian biotech hoping to receive a $25m milestone for FDA approval and a 20% profit on global sales. pSivida's Nasdaq listed stock fell 49% to $2.02 on Friday.

Both companies are now valued not much above current cash levels. Alimera held $39m in cash as of the end of September and is now worth $62m; pSivida's new market capitalisation of $38m compares to a cash reserve of $21m.

On a conference call with investors today Alimera provided little insight into the nature of the additional clinical trials required, preferring instead to talk up the chances of gaining approval in Europe and securing a commercial partner for this region. The company has also suspended recruitment and treatment in an ongoing 100-patient trial of Iluvien using a new inserter device; around 60 patients have been recruited so far.

Assuming the pivotal trial, dubbed Fame, was well designed and conducted it is hard to see Iluvien performing any better in two further clinical studies, in terms of providing the required efficacy and safety data to soothe the FDA's concerns.

EU reprieve?

Hence the keenness to talk about Illuvien's chances in Europe. The product was filed under the de-centralised procedure, with the UK as the reference member state. The UK's regulatory body MHRA is expected to make a recommendation shortly on Iluvien's approvability to the so-called 'concerned member states' of Austria, France, Germany, Italy, Portugal and Spain; a final decision is expected in the first half of 2012.

Alimera believes the market opportunity in Europe is similar in size to the US, where analysts had pencilled in sales of $400m by 2016, and is encouraged by the more proactive regulatory process in Europe – sponsors of new products tend to have more opportunity to be made aware of and then time to address any concerns the authorities may have.

As such, the company remains bullish about its chances of gaining approval in Europe and securing a commercial partner; negotiations are said to be ongoing.

As to Iluvien's American future, the follow up meeting with the FDA will be critical in determining whether Alimera presses on with the drug for DME. Although phase II trials are ongoing in age-related macular degeneration and retinal vein occlusion, the FDA's feedback, particularly the extent of its concerns over the adverse reactions linked to the drug, may yet put a brake on all further development.

Alimera's cash reserve is clearly sufficient to cover immediate needs, including completing the European

regulatory process, but embarking on further trials of Iluvien may stretch investor confidence and support beyond breaking point. Announcement of an often infamous ‘strategic review’ may not be far away.