Evaluate Vantage

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After fourth look FDA sees its way clear to approve Alimera's Iluvien

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Everyone loves a trier and Alimera Sciences' four year struggle to get diabetic macular oedema product Iluvien to US patients has finally paid off. Late on Friday the FDA finally handed the Georgia-based group the prize of US marketing authorisation it had been denied three times previously.

Given the wait it was unsurprising that shares in Alimera rose by 12% early trading to $5.49, but despite the gains the shares are still nowhere near the $11 at which they floated in 2010. The drug is also facing some stiff competition in the diabetic macular oedema space, and will need to make the most of its unique 36-month treatment duration if it is to carve out a lucrative space in an increasingly crowded market.

Back in February, Cowen was forecasting peak US sales for Iluvien of $565m and peak European sales of $312m. Since then Regeneron Pharmaceuticals' Eylea has received US approval, potentially cutting back on Alimera's market. As such Alimera will be selling Iluvien's compliance-aiding 24-36 month treatment duration to physicians.

However, there is a trade-off of an increased risk of cataracts and increased intraocular pressure. Which is why it was a surprise when the FDA awarded the drug a broad label. There had been concerns that Iluvien would only be authorised for use in subset of patients with chronic diabetic macular oedema, those who had failed other therapies, or had had cataract surgery, mirroring its approval conditions in Europe. The label, which is much less restrictive, should cause the few analysts who cover the stock to upgrade their forecasts.

If at first…

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, releasing the steroid over a 24-36 month period.

Alimera originally filed Iluvien for approval in 2010, but was denied when the FDA asked for 36 months' worth of safety and efficacy data, rather than the 24 months Alimera submitted (*Alimera gets unwelcome Christmas message from FDA, December 24, 2010*). Even with the addition of an extra 12 months data, the FDA was unconvinced that the risks of adverse reactions were offset by the benefits of the drug and asked for two more trials (*Alimera and pSivida strike out, November 14, 2011*).

The group's third and final rejection was based on statistic deficiencies in submitted data and some concerns over the manufacturing facilities for Iluvien.

Partner benefits

The other winner in Alimera's four year regulatory saga is pSivida, entitled to 20% of net profits from US sales the group will get as part of the licensing deal and also a $25m milestone. But what approval of Iluvien has also done is provide some de-risking of pSivida's sustained-release uvetitis treatment Medidur. Fluocinolone is the active ingredient in both Medidur and Iluvien, and pSivida will now be able to reference the Iluvien data in its single phase III study. Results are expected in early 2016.

Alimera is also unlikely to sit still too long and will be keen not only to use the money from US sales to help it launch in more European markets, but also to get Iluvien approved in the much larger wet and dry age-related macular oedema markets.

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