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Lucentis growth under threat again as Eylea scores another win

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Anything Lucentis can do, Eylea can do at least as well, it seems. Regeneron Pharmaceuticals and Bayer say they will be filing Eylea for approval in diabetic macular oedema (DME) in 2013, a year early, after positive interim results from a two-year trial.

The prospect of an earlier-than-expected approval will put the squeeze once again on the Roche and Novartis antibody Lucentis, which has seen stagnation in sales in its biggest indication, macular degeneration, as a result of competition. With another trial win, Eylea threatens Lucentis's main source of growth.

Good news, bad news

But Regeneron shares suffered, falling 5% to $257.60 in early trading today, because quarterly Eylea sales fell short of investor expectations. The New York-based group reported $330m in US sales, where it holds exclusive rights, while ex-US partner Bayer reported another $96m.

Thus it was fortunate that Regeneron was able to offer investors some good news. The Vivid-DME and Vista-DME trials were able to show a significant improvement in best-corrected visual acuity from baseline compared with laser photocoagulation at 52 weeks in a trial planned for two years.

Each study included two active arms, one in which patients received a 2mg injection each month and another in which they got the same dose once every other month after a five-month loading phase. Both regimens achieved significant improvement over the alternative treatment, in which heat from a laser beam closes blood vessels leaking fluid from the retina.

Eylea is a fusion protein that binds to vascular endothelial growth factor-A (VEGF-A) and placental growth factors. When injected into the eye it prevents the growth of abnormal blood vessels.

Regeneron and Bayer reported that following discussions with regulators they decided to submit Eylea for approval in the US and Europe on the strength of the one-year data, setting the stage for a launch in 2014. Most analysts had been counting on the FDA adding DME to the label in 2015, so a fair amount of revenue could be added to forecasts for 2014 and beyond.

Plateau coming

By 2018, DME is expected to account for 25% of forecast US sales of $2.98bn according to *EvaluatePharma*. The label expansion will come in handy as sales in the original indication, wet age-related macular degeneration (AMD), are expected to begin levelling off when new competitors enter.

Those competitors could include Lpath's antibody Isonep, which Pfizer has optioned for $14m; Allergan's VEGF-A antagonist MP0112, which emerged from Molecular Partners' DARPin platform; and ThromboGenics' Jetrea, recently approved in vitreal macular degeneration and in phase II in AMD.

Eylea has been the fuel driving Regeneron's incredible market valuation of $26bn, which stands well above the combined net present values of its marketed and R&D products. It needs to continue delivering good news on the eye drug – investors disappointed by short-term sales figures will return if the long-term growth story remains sound.

Study	Trial ID
Vista-DME	NCT01363440
Vivid-DME	NCT01331681

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