Evaluate Vantage

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Upcoming events – GW aims for Epidiolex expansion and NHL data from Epizyme

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Welcome to your weekly digest of approaching regulatory and clinical readouts. Next month GW is hoping to deliver a second successful phase III trial of Epidiolex in another rare type of epilepsy; the first study caused shares in the company to more than double.

Also in June Epizyme will present the first look at phase II data on its main asset, tazemetostat, in non-Hodgkin's lymphoma. The company bought the epigenetic project back from Eisai 14 months ago and has already promised to deliver a new partner this year, so it needs to generate a positive impression.

Epidiolex

Epidiolex data from a phase III trial in Lennox-Gastaut syndrome are due in June. The previous positive result in Dravet syndrome has increased confidence in a benefit in the second indication too – Morgan Stanley analysts have upped the project's probability of success from 55% to 75% in Dravet's and 60% in other indications.

Sales forecasts have also risen accordingly: Epidiolex is set to become a blockbuster by 2022, according to *EvaluatePharma* consensus.

Dravet affects 6,000 people in the US and Lennox Gastaut around 25,000 – so success in the latter will be a vital step towards meeting these expectations. Second phase III trials in both epilepsy types are also due later this year.

Both of the Lennox-Gastaut trials have a primary endpoint of change from baseline in the number of drop seizures, where a loss of muscle tone causes the sufferer to fall to the ground. Leerink analysts rate this as a robust endpoint with a small expected placebo effect, noting that other seizure types can be more subjective and therefore harder to count with precision.

Also contributing to high hopes for Epidiolex are promising data from an open-label study, as well as the first phase III trial in Dravet syndrome, which found a 26% reduction in seizures over placebo (*GW takes traders back to 2015, March 14, 2016*).

If GW manages to replicate this success it plans to file in both indications by the end of the year.

Tazemetostat

Next month Epizyme will present the first look at phase II data generated on its main asset, the EZH2 inhibitor tazemetostat, in non-Hodgkin's lymphoma.

The data are from a trial that is still ongoing and indeed recruiting patients; the company expanded the study earlier this year from 150 to 270. Patients are split into five arms depending on genetic signature; three cohorts are in DLBCL and two in follicular lymphoma. The results will be presented at the ASH Lymphoma conference in Colorado on June 18-21.

Because this is an early, interim look dramatic results are not expected, particularly as responses to tazemetostat take time to develop and strengthen, as was seen in phase I (*With efficacy box ticked, Epizyme faces economics question, June 22, 2015*).

Analysts at HC Wainwright only expect to see partial responses reported from the DLBCL groups, which the company recently said had passed a futility test. News on whether the FL arms have passed futility is awaited and could come at the conference, as should details on recruitment and the number of patients that remain on treatment.

Analysts view these results as setting the stage for the main ASH conference in December, when a much fuller dataset will allow a more rigorous assessment.

However, with the company also flagging a deal for tazemetostat anytime now, any bad news is likely to hit the stock substantially.

Project	Indication	Trial ID	Primary completion
Epidiolex	Lennox-Gastaut syndrome	NCT02224690	Mar 2016
Epidiolex	Lennox-Gastaut syndrome	NCT02224560	May 2016
Epidiolex	Dravet syndrome	NCT02224703	Jul 2016
Epidiolex	Tuberous sclerosis complex	NCT02544763	Jul 2017
Tazemetostat	NHL	NCT01897571	Sep 2017

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