Evaluate Vantage

June 05, 2015

Upcoming events – Tysabri in progressive MS and Sativex in cancer pain

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Welcome to your weekly digest of approaching regulatory and clinical readouts. A phase III trial of Biogen's Tysabri in secondary progressive multiple sclerosis will report in the summer, as will a phase II in stroke.

And, after its first pivotal trial failed to show that Sativex can relieve cancer-related pain, GW Pharmaceuticals needs its second trial to return positive results if it wishes to expand sales of the cannabis-based product.

Tysabri timing

Having obtained approval for Tysabri in relapsing-remitting MS, Biogen is now pushing to expand the label into the secondary progressive form of the disease. The Ascend in SPMS trial will assess the effect of Tysabri on the rate of accumulation of disability not related to relapses in comparison with placebo in 890 SPMS patients.

Around 80% of RRMS patients develop SPMS and as only one product has obtained specific approval for SPMS – mitoxantrone, now generic – there is a major opportunity in this space. Analysts at Bernstein estimate that an SPMS label could add $1-1.5bn to Tysabri's revenues in the US alone. It would also expand the drug's patent life.

But the trial may be a more significant event for one of the other companies with an interest in Tysabri: Perrigo. The group is entitled to royalties of 18% on Tysabri's global sales up to $2bn and 25% for sales over this amount.

Were an approval for SPMS to add $1bn to Tysabri's sales, Perrigo would receive a further $250m in royalties. With a shareholder vote on Mylan's takeover bid for Perrigo scheduled for around the same time as the trial reads out, the phase III data could be a catalyst for more than just the share price.

Second Sativex cancer pain trial

If GW Pharma is to have any chance to expand sales of Sativex into cancer-related indications, the remaining phase III trial due to report later this year must prove that the oral spray can significantly reduce chronic pain in patients taking an optimised dose of opioids.

The UK-based group failed to show this in an initial trial in 380 patients (*GW investors follow the script after Sativex miss, January 9, 2015*). The second study may have a better chance given its enriched design.

The two-part trial involves exposing all patients to Sativex for a two-week period, after which responders will be re-randomised to take either Sativex or placebo. The enrolment goal was 540 patients to enter the initial phase, with 216 moving into the randomised stage.

Sativex is approved to control muscle spasticity in multiple sclerosis in several European jurisdictions. However, this does not look likely to generate huge sales, with main European partner Almirall forecast to bring in $53m in revenues by 2020, up from $20m last year. Otsuka has US rights to the drug in both the muscle spasticity and cancer pain indications.

Cancer-induced pain is a much larger market than the spastcity indication. But much of the focus of GW investors is now on follow-up drug Epidolex, which is in phase III trials in the epileptic conditions Lennox-Gastaut syndrome and Dravet syndrome.

Success for Sativex in cancer pain might come as a pleasant surprise.

Trial name	Trial ID
Ascend in SPMS	NCT01416181
Action	NCT01955707
Sativex cancer pain	NCT01424566

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