Europe eases Tysabri safety concerns

Vantage News Team

Having just graduated to a blockbuster selling product, Tysabri’s chances of further commercial success received a boost yesterday when a European advisory committee issued a largely favourable opinion of Elan and Biogen Idec’s vital MS drug, alleviating fears that long-term use of the drug could be curtailed to reduce the risk of PML (Surge in PML cases could send Tysabri on extended holiday, October 26, 2009).

A sudden surge in cases of PML in October, mainly in patients receiving Tysabri for more than two years, prompted the European review of the drug, but this now looks like a blip as rates have moderated in recent months. The committee concluded that the benefits of Tysabri continue to outweigh the risks, even after two years, and the only recommended changes to current practice refer to increased PML-risk awareness and the signing of consent forms; as benign an outcome as Elan and Biogen could have hoped for.

PML rates stabilise

Yesterday’s report by the European authorities stated 31 confirmed cases worldwide of PML associated with Tysabri since its reintroduction in 2006. This translates into a current PML rate of 2.5 cases per month, significantly lower than the 6.5 cases per month in September and October which caused such a stir.

Of the 31 cases, 23 had received Tysabri for more than two years, painting an increasingly convincing picture that the risk of PML is strongly linked to treatment duration. However, even in this extended treatment group, the risk of developing PML is one in 1,000, a pretty low risk rate considering the patient population of very ill MS patients receiving Tysabri who are likely to accept these odds.

Given the stabilising PML rates and the fact Tysabri is really the only treatment option available to MS patients who have failed to respond to standard interferon therapy, the committee naturally voted in favour of keeping the drug on the market and importantly without any changes to current prescribing practice.

The only real difference is that patients will have to re-sign a consent form if treatment extends beyond two years following a reappraisal with their doctor. This will come as a huge relief to both companies given their reliance on Tysabri, to fuel Biogen’s sales and earnings growth and help turn Elan into a profitable company by 2012.

Shares in both groups, which had already recovered the losses suffered in October, were flat in early trading today.

Awaiting a JC virus test

PML is a rare brain infection thought to be caused by the JC virus, a virus commonly found in the general population but which only leads to PML if a person’s immune system is weakened, such as in MS patients receiving immunomodulating drugs like interferons and Tysabri.

Elan has said previously that 25% of confirmed PML patients have been tested for the JC virus and that all 25% returned positive results, supporting the theory that the virus has a causal and predictive relationship with PML.

Although Elan has so far shied away from announcing anything official on its plans for a JC virus test, it is widely understood that the Irish group is currently developing one and that a test could be available this year.

Assuming that further analysis of the PML patients confirms the relationship with the JC virus and that a robust test can be developed, this is significant as it will help to alleviate PML concerns for non-carriers of the virus while highlighting the carriers which will need to be monitored closely to spot the symptoms as early as possible.

More music?
It is estimated that 60% of the adult population carry the JC virus, having contracted it during childhood with minimal infection of adults. This does not mean that Tysabri’s potential patient population will be reduced by 60%, given the aforementioned lack of alternative therapies and relatively low odds of developing PML.

Meanwhile, for the 40% of MS patients without the JC virus, patients and doctors will be much more comfortable using Tysabri, enabling the drug to be used more widely than currently expected.

Consensus estimates from EvaluatePharma put global sales of Tysabri at $1.58bn by 2014, yet analysts at UBS suggest the drug could become a $5bn - $6bn seller if the PML risk can be managed and reduced by a JC virus test and better understanding of Tysabri’s relationship with PML.

More music to the ears of Biogen and Elan.