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Physician Views: As Tecfidera approaches a critical juncture in Europe, how are neurologist perceptions towards Biogen Idec's MS drug shaping up?

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Abstracts

Sales of Biogen Idec’s multiple sclerosis therapy Tecfidera may continue to exceed initial expectations in the US market, but in Europe a shadow of doubt has been cast across the future of the drug.

On the company’s Q3 earnings call, management confirmed that the European Medicines Agency's Committee for Medicinal Products for Human Use is expected to make a final decision on regulatory data protection (RDP) for Tecfidera on or shortly after November 22. Biogen Idec is now reportedly looking to secure new active substance (NAS) for the product.

That decision is seen as being critical in determining whether Biogen Idec launches Tecfidera in the EU; in the advent that no RDP is granted, there is a clear rationale for Biogen Idec not to launch the drug, argue analysts, given both the direct threat of short-term generic competition and the indirect impact of said competition on the company's other MS franchises. See ViewPoints: Tecfidera sales soar, but 'all or nothing' EU decision on data exclusivity looms for Biogen Idec.

An exceptional US sales growth performance for Tecfidera is a clear barometer of how this product has been embraced by both neurologists and patients since its launch in April, supported by positive key opinion leader feedback. Similarly, there is evidence to support the view that anticipation among European neurologists is equally high.

When FirstWord polled 138 EU5-based neurologists in June, respondents indicated that on average they were 'warehousing' 12 percent of newly diagnosed MS patients for treatment with Biogen Idec’s oral therapy. Last month, analysts at Leerink Swann

informed investors of significant 'pent-up demand' for Tecfidera, suggesting that should a launch not materialise on RDP grounds there could be a 'community-wide backlash' (see ViewPoints: Delayed launch for Biogen Idec's Tecfidera said to be causing 'quasi-hysteria' among European MS patients).

With Tecfidera now approaching what appears to be a critical juncture in Biogen Idec's European regulatory process, FirstWord is this week polling neurologists based in the EU5 to ascertain how perceptions around Tecfidera have shifted over the past six months. Specifically neurologists will be asked:

> What percentage of diagnosed relapsing remitting MS patients are you warehousing in anticipation for treatment with Biogen Idec's Tecfidera?
>
> Has this percentage of patients increased or decreased over the past six months and by what percentage?
>
> What percentage of patients initially warehoused for treatment with Tecfidera have you subsequently begun treating with an alternative therapy due to Tecfidera's delayed launch in the EU?
>
> Assuming Tecfidera was to launch in early 2014 – what percentage of total (i.e. newly diagnosed and existing) relapsing remitting MS patients would you anticipate treating with the drug in a first-line setting by the end of next year?
>
> What percentage of patients currently treated with another oral therapy (i.e. Novartis' Gilenya or Sanofi's Aubagio) would you switch to Tecfidera assuming launch of Biogen Idec's drug in early 2014?

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