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Keryx and Galenica face a tough battle to build phosphate franchises

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Approval for Keryx's ferric citrate heralds the launch of a second novel phosphate binder in the US, in the wake of Galenica's Velphoro earlier this year. Both face a tough fight for share of a market beset by generic competition and already grappling with new regulatory frameworks.

Concerns that a weaker than expected label will make Keryx's job much harder and uncertainty around its patent situation have contributed to an 18% drop in the company's shares since news of the approval. But this was always going to be a tricky launch; Galenica has said that Velphoro will take time to establish itself, and the Swiss company has the advantage of a pre-existing deal with dialysis centres.

Galenica's caution is notable given that in the US the drug is being sold by Fresenius Medical Care (FMC) as part of a joint venture; FMC runs about a third of the dialysis centres in the US so Velphoro would presumably have a ready-made market. Hypophosphataemia, which all these drugs treat, occurs in dialysis patients because of impaired kidney function.

Despite launching Velphoro in early 2014 Galenica has yet to reveal sales figures, only revealing that single-digit revenues had been generated in the first half; analysts assume that sales hit around Sfr5m ($5.3m). Peak sales are estimated at around $300m.

The drug's selling point is a much lower pill burden than the soon-to-be generic market incumbent, Sanofi's Renvela – on average 3.3 pills per day are required to normalise phosphate levels, compared with almost nine for Renvela.

USPs

Keryx's contender – formerly called Zerenex until the FDA turned down the name – also requires around nine pills a day. The company had instead hoped to push ferric citrate's ability to reduce the need for intravenous iron and red blood cell-boosting erythropoietin stimulating agents (ESAs).

These therapies are often required to treat the anaemia that patients with kidney disease suffer and, because they are injected, they now have to be paid for by dialysis centres out of the "bundled" payment that the CMS imposed in 2011. This sought to cap the amount of money Medicare was paying to treat each patient.

The bundled payments have hit the independent dialysis centres particularly hard, and it is these that represent the most obvious market for Keryx. By pointing to clinical data showing that ferric citrate was associated with a 24% reduction in the need for ESAs and a 52% reduction in IV iron, the group was hoping to persuade centres that opting for ferric citrate would help cut costs elsewhere.

However, the FDA refused to allow this data on the label, or for any claim to be made in this regard. Instead, because ferric citrate also causes iron stores in kidney patients to increase, it slapped on a warning describing the risk of iron overload.

Executives from the company believe that this can still be turned into a positive differentiating attribute – the warning will be read by doctors as speaking to the overuse of IV iron, they contend – and cash-strapped centres will appreciate the cost-saving potential.

Some agree with this stance. Analysts who cover Galenica for UBS, for example, wrote that many clinics, particularly the small centres, would translate the warning into a cost benefit. However, others believe that the label will restrict its potential; FBR Capital Markets halved its peak sales number for ferric citrate to $476m, for example.

Adding to concerns about the company are patent issues – the FDA has so far refused to confirm new chemical entity status for ferric citrate, which comes with five years' rock-solid market exclusivity. Plus there is the fact that Keryx is a small company going it alone; history suggests that this is rarely a recipe for success.

Hurdles ahead

The arrival of ferric citrate looks likely to make Galenica's life tougher outside centres financially incentivised to use Velphoro. And the label that Keryx has to work with – even when reading it as a marketing advantage as opposed to a red flag – can hardly be considered best case.

At the same time both will have to grapple with mounting pricing pressure. Generic versions of the entire Renvela franchise arrive next week; this franchise generated $996m for Sanofi last year.

Given the hurdles ahead, it seems highly unlikely that either new product will knock on the door of blockbuster sales.

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