Evaluate Vantage

November 28, 2013

Galenica rests PA21 hopes on dosing and partnership

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The next test for Galenica's hyperphosphataemia drug Velphoro is whether its dosing advantage and business development strategy will enable it to gain market share in the dialysis treatment space. The FDA's approval of the oral phosphate binder formerly known as PA21 sets up a battle against Renagel, the Sanofi pill that will lose patent protection next year, as well as a potential new rival in Keryx Bioharmaceuticals' Zerenex.

A reduced pill burden and a guaranteed buyer through a joint venture with dialysis provider Fresenius Medical Care could be sufficient for Velphoro to achieve as much as $300m a year in peak sales, analysts believe. The main question is whether Fresenius will be able to resist payer pressure to use cheaper Renagel generics as the US clamps down on dialysis expenditures.

Taking fewer pills

Hyperphosphataemia occurs in dialysis patients because of impaired kidney function, and can cause complications in the skeleton and other organs. Renagel, Velphoro and other treatments work by binding with dietary phosphorus and preventing it from being absorbed in the gastrointestinal tract.

Velphoro is a more potent phosphate binder, requiring just one pill with each of three meals to reduce phosphorus levels. By comparison, Renagel's label suggests up to 12 pills a day, depending on serum phosphorus, whether the patients have taken a phosphate binder and the pill dosage. Galenica argues that up to half of dialysis patients do not achieve phosphate targets, in many cases because of the pill burden; the average dialysis patient takes 19 a day.

A launch early next year would put Velphoro a few months ahead Renagel's patent expiry in September 2014. This would normally raise questions about whether Velphoro has much of a chance of earning hundreds of millions of dollars in sales, but the partnership with Fresenius gives it a better prospect (*Upcoming events: FDA to decide on Sovriad and PA21, November 22, 2013*).

Fresenius runs about a third of the dialysis clinics in the US and stands to receive a reimbursement rate from US Medicare at 6% above the purchase cost. In addition, Fresenius will receive 45% of the profit from the joint venture.

Should Velphoro only be prescribed at Fresenius clinics it still could achieve $300m a year in peak sales, analysts from UBS believe. Analysts at Deutsche Bank have forecast more modest peak sales of $200m a year.

Only in 2016, when oral drugs become part of the "bundled" episode-based payments imposed under Medicare reforms could the economics change for Fresenius, the UBS analysts add (*Event – US dialysis Medicare cut could be counterproductive, October 23, 2013*). And even then it would take the entry of numerous generics and a big drop in prices to erode the benefits of Velphoro for Fresenius completely.

Shares in Switzerland-based Galenica rose 4% to SFr904.50 in mid-afternoon trading.

Innovation a threat

However, the main competition could emerge not from generics but from another innovative product, Keryx Pharmaceuticals' Zerenex. This is iron-based, reducing the need for intravenous supplementation, and in addition has been shown to reduce the need for erythropoietin-stimulating agents, one of the most expensive items in the bundle (*Zerenex data heralds a tricky future for Keryx, January 29, 2013*).

Zerenex is due an FDA approval decision in June, so it will be important for Galenica to have established a presence by then. Analysts have forecast a more optimistic picture for the Keryx candidate – nearly $400m in sales by 2018, according to *EvaluatePharma* consensus.

The dialysis space has more uncertainty than most, not the least because it has more regulatory risk than most, and will also see significant generic erosion. To achieve $300m a year in sales with Velphoro as the optimistic analysts are forecasting Galenica needs to hope its joint venture with Fresenius holds up in the face

of these pricing pressures.

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