PRESS RELEASE

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Subject Velphoro® receives EU Marketing Authorisation

Velphoro® receives EU marketing authorisation for treatment of hyperphosphatemia in adult CKD patients on dialysis

Velphoro® (sucroferric oxyhydroxide) has received EU marketing authorisation from the European Commission for the control of serum phosphorus levels in adult patients with Chronic Kidney Disease (CKD) on haemodialysis or peritoneal dialysis. In June, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending marketing authorisation for the product.

Velphoro® is a non-calcium, iron-based, chewable phosphate binder. The EU marketing authorisation for the 28 EU countries was based on a pivotal Phase III study which met its primary and secondary endpoints. The study demonstrated that Velphoro® successfully controls hyperphosphatemia with fewer pills than sevelamer carbonate, the current standard of care in patients with CKD on dialysis[1]. The average daily dose to control hyperphosphatemia was 3.3 pills per day after 52 weeks.

Hyperphosphatemia, an abnormal elevation of phosphorus levels in the blood, is a common and serious condition in CKD patients on dialysis. Most dialysis patients are treated with phosphate binders, but up to 50% of patients – depending on the region – are unable to achieve and maintain their target serum phosphorus levels[2]. In some patients, non-compliance due to the high pill burden and poor tolerability appear to be key factors in the lack of control of serum phosphorus levels[3,4]. On average, dialysis patients take approximately 19 pills per day with phosphate binders[5] comprising approximately 50% of the total daily pill burden. The recommended starting dose of Velphoro® is three tablets per day (one tablet per meal), and Velphoro® could therefore help to improve phosphate management and improve outcomes in patients who currently do not comply with treatment due to the high pill burden.

Velphoro® was developed by Vifor Pharma, which produces the active ingredient in Switzerland. All rights were transferred in 2011 to Vifor Fresenius Medical Care Renal Pharma, a common company of Galenica and Fresenius Medical Care. Velphoro® was approved by the US Food and Drug Administration (FDA) for the control of serum phosphorus levels in patients with CKD on dialysis in November 2013 and launched in the US by Fresenius Medical Care North America in March 2014.

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Galenica *is a diversified Group active throughout the healthcare market which, among other activities, develops, manufactures and markets pharmaceutical products, runs pharmacies, provides logistical and database services and sets up networks. With its two Business units Vifor Pharma and Galenica Santé, the Galenica Group enjoys a leading position in all its core business activities. A large part of the Group's income is generated by international operations. Galenica is listed on the Swiss Stock Exchange (SIX Swiss Exchange, GALN, security number 1,553,646).*

For more information, please visit the company's website at www.galenica.com.

Fresenius Medical Care *is the world's largest integrated provider of products and services for individuals undergoing dialysis because of chronic kidney failure, a condition that affects more than 2.3 million individuals worldwide. Through its network of 3,225 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatments for 265,824 patients around the globe. Fresenius Medical Care is also the world's leading provider of dialysis products such as hemodialysis machines, dialyzers and related disposable products.*

For more information, please visit the company's website at www.fmc-ag.com.

Velphoro® *(**PA21)** is a chewable, iron-based phosphate binder containing a mixture of polynuclear iron (III)-oxyhydroxide, sucrose and starches. Each tablet of Velphoro® contains the equivalent of 500mg of iron. When taken with meals, Velphoro® adsorbs the dietary phosphate in the gastrointestinal tract and prevents its uptake into the blood. The adsorbed phosphate is subsequently eliminated through the faeces.*

The Velphoro® Phase II clinical trial met both its primary and secondary endpoints. The serum phosphorus lowering efficacy of the two lowest active doses was numerically comparable to 4.8g/day sevelamer hydrochloride. Velphoro® was also well tolerated, with a comparable overall safety and tolerability profile.

The Phase III trial was an open-label, randomised, active controlled, parallel group study to investigate the safety and efficacy of Velphoro® compared to sevelamer carbonate, followed by a randomized comparison of Velphoro® maintenance dose versus Velphoro® inactive low-dose in dialysis patients with hyperphosphatemia.

Velphoro® is developed in collaboration with Fresenius Medical Care (www.fmc-ag.com). It is also currently undergoing Phase III clinical development in Japan by Kissei Pharmaceutical Co., Ltd.

References

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